Thursday, 17 November 2022

(10.00 am)

(Proceedings delayed)

(10.15 am)

SIR BRIAN LANGSTAFF: Good morning to all of you. Good morning again in your case, Professor Dillon.

PROF DILLON: Morning.

SIR BRIAN LANGSTAFF: Now can you hear me, Dr McClean?

DR McCLEAN: Yes, I can.

SIR BRIAN LANGSTAFF: Good. And you can see me?

DR McCLEAN: Yes, I can. Thank you.

SIR BRIAN LANGSTAFF: Good. Then we are ready to begin. Let me explain the arrangements so that you all know. You're not just talking to the audience immediately in front of you but to those who are sitting in a breakout room beyond this room and who are watching on live stream or YouTube. The total figure will be in the region of three figures somewhere, can't say exactly.

To the left there are lawyers who represent various interests in the Inquiry. In the back left there are representatives of the press. So that's your audience, apart from me, of course.

In a moment or two, Ms Fraser Butlin will ask you the questions. But first, Mary will ask each of you in turn to give your respective oaths.

PROFESSOR GRAHAM RUSSELL FOSTER (affirmed)

PROFESSOR JOHN FRANCIS DILLON (sworn)

DR BRENDAN HEALY (affirmed)

DR JOANNE MCCLEAN (affirmed)

SIR BRIAN LANGSTAFF: Yes.

Questioned by MS FRASER BUTLIN

MS FRASER BUTLIN: Thank you.

Professor Foster, if we can start with you. You are NHS England's national clinical lead for hepatitis C and national clinical chair for the NHS England's hepatitis C elimination programme.

PROF FOSTER: That's correct.

MS FRASER BUTLIN: Could you tell us what those roles involve?

PROF FOSTER: So I was appointed to the national roles in around 2015. My main focus is providing clinical advice and support to the NHS England hepatitis C elimination team. So that will involve attending the appropriate meetings, providing advice and guidance, recommending strategies, and essentially liaising with clinical colleagues trying to make sure that the clinical opinions are heard at the commissioning level.

MS FRASER BUTLIN: And you discuss in your statement the hepatitis C elimination plan, and you say there that the programme has been funded by NHS England but that the

pharmaceutical companies who sell the drugs for treating hepatitis C also have a contractual obligation to invest in elimination initiatives.

PROF FOSTER: That's correct.

MS FRASER BUTLIN: Can you explain for us what that means, that pharmaceutical companies are -- what are they involved in?

PROF FOSTER: This goes to a large-scale procurement that initiated about five years ago when we recognised that the pharmaceutical companies had skill sets that could be useful to us in an elimination programme. And we realised that if we collaborated with the pharmaceutical industry, we could achieve more than we could in isolation. So we put forward a procurement programme and the programme said the drug companies had to put their best price forward and they had to put forward elimination initiatives and they had to agree to fund those initiatives. All of those were then scored in a very complex legalistic procurement process that led to an awarding of market share. So each of the drug companies is allowed to sell no more than X per cent of their particular product.

So what that means in reality is that instead of a drug representative coming into my clinic and saying, "I want you to use drug X because it's better than

drug Y", they come into the clinic and say, "We want to find more patients."

So we have the bizarre situation sometimes where a drug company will recommend a competitor's product so that the patient can get better treatment, because they know if they're treated with a competitor's products there will be a corresponding increase in their performance because the market share is fixed.

I think that's been a great success. It took a year or two to bed in. It was a very difficult working relationship to begin with, but it means that everyone is working on finding people with hepatitis C and getting them on treatment as quickly as we can.

MS FRASER BUTLIN: And in terms of those initiatives, does this mean that pharmaceutical companies themselves are undertaking initiatives to find people **(The witness nodded)** or that they're funding NHS England initiatives?

PROF FOSTER: It's a combination. So there is, for example, direct funding from pharmaceutical companies. They will buy, for example, point of care testing machines and install them in places, they will put them in places where NHS England recommends. There are areas where they clearly can't go. They can't have access to patient information, they can't have access to GP records, et cetera, et cetera, and there they would work

through us.

So each initiative is a joint approach with appropriate funding streams, appropriate governance streams, depending on where the particular strengths lie.

So, to give you an example of where this is able to expedite performance, is in treating people in injecting drug services, because injecting drug services are not commissioned by NHS England; they're commissioned by local authorities. So NHS England has no authority and so I cannot go into an injection drug service supplier, but a pharmaceutical company can and they can make changes and recommendations.

I talked a moment ago about the point of care testing machines. To get a point of care testing machine through the NHS requires a fairly lengthy bureaucratic process, validating and supporting a procurement process. The pharmaceutical company can access those machines very quickly and have them in place within weeks rather than months. So we try to use their skills where appropriate.

MS FRASER BUTLIN: And when you spoke a moment ago about data that pharmaceutical companies couldn't access so they went through NHS England, just to be clear, I think what you mean is that they would fund somebody in

NHS England to deal with that data rather than that any of that data would ever go to the pharmaceutical companies?

PROF FOSTER: Pharmaceutical companies under no circumstances can ever have access to any patient's individual protected data. What they do get are aggregate figures to say, "This month we have treated X hundred patients". So they never get patient level data. Indeed, commissioners at NHS England -- as an NHS commissioner, I'm not allowed to see individual patient data. Commissioning is patient agnostic and anonymised from start to finish.

MS FRASER BUTLIN: You've talked in your statement about there being three phases to the elimination programme. Phase 1 relating to the provision of oral therapies, phase 2 focused on particular at-risk groups. What can you tell us about what phase 2 involved?

PROF FOSTER: So if I set the stage perhaps with the constraints that we commission under. The -- our first use is always to look at what resource we are going to deploy on a particular programme. And resource is not just about money; increasingly it's about people and skills. So we're very aware that if, for example, we ask primary care physicians to do a series of tests for hepatitis C, they will not be doing a series of tests in

something else. So if they're testing everybody for hepatitis C, they are going to have to stop testing for diabetes or cardiovascular disease. So, in a fixed resource environment, which is where we work, we try to weigh up where we're going to get maximum advantage, and we need to be very careful that we don't have inappropriate consequences and reduce access to services in other areas.

So the first constraint we have is -- in crude terms, how much bang do we get for our buck? Where can we get best advantage? The second constraint is equity, and NHS England does not distinguish by mode of acquisition of disease; we focus on priority and need. We appreciate that individuals may have different views, but our focus is always to try to provide an equitable, equal service, regardless of how people contracted their particular problem.

So within those constraints, when we started our programme we had very limited access to drugs, the drugs were very expensive, and there was a cap on the number of treatments that we could give. And to begin with, we didn't know how effective they would be in the real world. So we started our focus on people with decompensated cirrhosis, very advanced liver disease, and then very quickly we moved to an understanding that

the treatment was safe, as effective in the real world as it was in the clinical trials. And we started to negotiate a much better deal.

So at that stage we set up a "Go" for Hepatitis C Elimination programme. The first thing we did was to institute a sort of facilitatory treatment atmosphere. We did that by dividing the country into networks, operational delivery networks, and each of those networks was given treatment targets, and those were challenging treatment targets. I had a series of emails from people saying, "We really can't find all of these". And if people didn't hit those treatment targets, there was a very significant financial penalty. When I say significant, in the millions of pounds terms for some trusts. So we incentivised people to go out and find patients.

We then put a per-treated patient fee. So every patient treated gets a £500 fee from NHS England. So that's an environment that really incentivises and drives people to get as many hepatitis C patients as they possibly can. It has led trusts and organisations to invest in hepatitis C elimination. So that set the soil for the initiatives.

We then set up a whole variety of initiatives focusing on different patient populations. I think the

ones that are of main interest to the Inquiry are those looking for people who might have been infected by contaminated blood or blood products.

The main focus to begin with was looking at people who were known to have hepatitis C who had a diagnosis, and we knew there are a lot of people with positive test results that haven't been offered treatment, haven't been properly supported. So we wanted to get all of those patients. We made it a condition of the networks that they had links to the local virology service, so they would have access to all the previous tests and, with our colleagues at Public Health England, we had a re-engagement exercise and that re-engagement exercise looked at all of the positive hepatitis C tests. We cross-referenced to those that we knew had been treated and removed those and that gave us a list of about 50,000 people who we contacted individually to check their hepatitis C status and offer treatment.

So that re-engagement exercise found, we hope, a large proportion of the people with hepatitis C.

As I mentioned in my statement, we've got a number of other initiatives that are ongoing and I'm happy to go into those now or defer as you prefer.

MS FRASER BUTLIN: If we can just pause on the exercise of identifying those people who had a previous positive

test but, for various reasons, hadn't been treated. You said you ended up with a list of about 50,000. Do you have any figures -- and you may need to provide them later -- of how successful that exercise was?

PROF FOSTER: So, unfortunately, as the programme was being evaluated and Public Health England had an audit and assessment of that, the coronavirus pandemic struck, and that diverted resource. So the audit has not been completed. The preliminary data that I've seen suggested about 10 per cent of the people who were on that list had a positive hepatitis C test and went on to treatment. So it was about one in ten were caught and treated, but I don't have a denominator for that, I'm afraid.

MS FRASER BUTLIN: Could you help us then what was the position in relation to the other nine out of ten?

PROF FOSTER: So a lot of people had false positive tests. A large proportion of people had been treated. We never had records of people treated in the interferon era; we only have records of people treated in the oral medication era so a lot of people have been treated. A surprisingly large number of people can access treatment in other ways and, outside the NHS, there are ways of purchasing the oral anti-viral therapies and a significant number of people, quite a surprisingly

large number of people, had gone to websites, purchased treatments, taken it themselves. Quite a lot of people of Pakistani heritage had gone back to Pakistan and bought treatment there where it was cheap and, interestingly, they were keen to engage with us to test that the treatment had actually worked.

So it was a whole different variety of different reasons for people who hadn't been -- who tested negative on retesting.

MS FRASER BUTLIN: Again, this may be something you need to tell us at a later date, but of that 50,000 roughly how many of them could you not find? The Inquiry has heard evidence about previous look-back exercises where there have been difficulties finding patients.

PROF FOSTER: I would have to revert to my Public Health England colleagues and their audit to give you that detailed data but during the process we had NHS numbers, GP records and Public Health England were able to give us an active phone number that was on the GP records, so we'd already sieved out patients who'd had no obvious contact point.

A proportion clearly weren't contactable and those that weren't contactable we wrote to the GP and said, "We have tried to contact this patient. Next time this patient attends your surgery can you please arrange

a hepatitis C test". So I don't unfortunately have the data and I suspect that -- because the audit was never completed I rather suspect that data won't be readily available.

MS FRASER BUTLIN: In terms of the other initiatives that were taken in phase 2, they were primarily focused on particular risk groups, weren't they?

PROF FOSTER: So as we moved into an expansion of the programme, one of our priorities was people who were transmitting the virus because, clearly, if we're going to eliminate hepatitis C, we need to stop the virus transmitting and the people who were transmitting the virus were people who were disengaged from healthcare services and treatment provision in needle exchange centres; people who were injecting drugs were very poor at that time. So one of our major priorities was to get treatment into injecting drug services, make sure the homeless populations, the disadvantaged populations, had access to therapy so they would not transmit to others.

And that was run in parallel with the GP screening, the awareness raising in primary care and, as I'm sure we'll come on to in a moment, our GP track and trace tool.

MS FRASER BUTLIN: Which we will come to. But, before we leave phase 2, I think there was also some work done in

relation to patients known to services, to double check their status in relation to patients with haemophilia or who also had HIV infection and to check whether there was co-infection.

PROF FOSTER: We worked -- the patients who were in haemophilia services -- we have, as you know testing regimes for people in haemophilia services. We incentivise people to go and find those people early on and get from offered treatment as we expanded. It sounds rather facile to say but, in a way, they are probably the easiest patients to find, they are in services, heavily engaged in healthcare and treatment, once we established that it was efficacious and widely available, was very easy to deploy. So I think that we have probably offered anti-viral therapy to all patients in haemophilia services and we work with haemophilia services to confirm that.

MS FRASER BUTLIN: Then we come on to phase 3. You've described phase 3 as identifying people at risk of infection who haven't been tested and, in your statement, you've identified six measures that are being implemented. If we can take them in turn. First of all, work to encourage testing in primary care. What has that involved?

PROF FOSTER: So we've written a number of articles to

primary care colleagues, had a number of primary care advisory boards. We have, it's fair to say, found our primary care colleagues distracted by the coronavirus pandemic, and we have not had the engagement that we would have wished. We're just recruiting, as in put out job adverts, for what we call GP Champions and we're going to pilot those in London.

So we're going to appoint a small number of general practitioners with a particular interest in hepatitis C who will encourage their colleagues to engage with us. They will also, I hope, undertake some of the basic chores of going through general practice lists, identifying patients at risk. So I hope the GP practice Champion model will work. It worked very well in HIV increasing testing rates, so we'll see if that works in London and, if that is successful, then we'll roll it out nationally.

MS FRASER BUTLIN: Secondly, you've talked about an online testing portal. Could you tell us what the aim of that portal is?

PROF FOSTER: There are really several groups of patients that are not accessing proper testing at the moment. There's group of people who have risk factors that they would prefer not to divulge. There's group of people who find it inconvenient to go to their primary care

physician and there's group of people who are worried by stigma of hepatitis C, and all of those three groups are areas that we want to target.

So the intention is to set up a website, and we are going through the procurement process now that's been completed, a preferred bidder has been selected, and we're working with them on the design of the website and, hopefully, that will be live before Christmas. So anyone will be able to go into the website, in the website, they will land on an appropriate landing page. So if you've been referred by your primary care physician you will go to a page that says, "Your doctor has recommended, here's what you do". If you've gone to it from an Urdu -- or foreign language, then you'll land on a foreign language site. If you've gone into it as an interested member of the public, you'll be directed to a page that says, "You might need a hep C test if".

So the idea is that we will have different landing pages and those are being worked through at the moment and how many end up with and what they'll look like, I couldn't tell you at the moment.

But people will then go in, request a test, they'll be sent thorough the post a needle stick lancet and a tube, and put the sample in the tube and post it off. That's worked very successfully in HIV testing and

sexual health, as well as coronavirus testing, so we believe that will be acceptable to people, and we've done some focus group work to see whether people prefer an oral swab or finger-prick swab.

When the result is obtained by the laboratory, if it's negative the patient will be contacted directly to say "You are hepatitis C negative". If it's positive, the result will be passed on to the local hepatitis C treating centre who will be contact the patient directly.

We don't want patients with a positive test getting a phone call that says, "You've got hepatitis C, you'll have to do something about it". We don't want them getting an email or a text, we want them supported by someone who will say, "You've got hepatitis C, I'm a nurse, who will help you treat it. Here's what you need to do and here's what will happen". So we want to make sure they have counselling and support.

I hope that will be live before Christmas, whether it will be live in its entirety or whether it will be a section of it, I can't tell you at the moment but the hope is that that will be up and running in its full form by early next year.

MS FRASER BUTLIN: You spoke a moment ago about there being foreign language pages as well. When the result is

provided, if it's a positive result, to the local treatment centre, what provision will there be to deal with those language or, more significantly sometimes, the cultural barriers that somebody faces in even engaging with the treatment centre?

PROF FOSTER: We're very aware of the high prevalence of hepatitis C in some of our immigrant communities, I have particular interest in the Pakistani community and have done some work out in Pakistan, so we have appropriate language speakers. We also have peers with lived experience of hepatitis C from those countries, who can talk to the individuals in the appropriate language. The main languages we're looking at are the Eastern European and Urdu speaking.

MS FRASER BUTLIN: Your third measure that you deal with is work being done in introducing testing in emergency departments. What can you tell us about that?

PROF FOSTER: This is now live in London and everyone who goes into an NHS emergency department in London will see a poster that says "In this department we test everyone for viral hepatitis and HIV". If they have a blood sample taken, the treating physician will tick a single box and that single box will trigger a blood request form for HIV, hepatitis B, and hepatitis C tests. Those will be processed in the laboratory and the patients who

are positive will be informed, and there are information leaflets that say, "No news is good news. If we don't phone you, you do not have any of these infections".

So we will contact patients from the centre, and there's a triage process, whereby patients are contacted and offered an appointment. If they don't respond to that they're contacted a second time. If they don't respond to that, then their GP is informed and their notes are flagged.

We're now running throughout London. I have to say, that we have found huge numbers of hepatitis B, several hundred per month, so a very large number of hepatitis B patients in London that were undiagnosed; relatively few hepatitis C patients, in the tens of patients per month, of which a large proportion are already known to services; and a handful of patients with HIV. In fact, the HIV and the hepatitis C numbers are roughly similar at the moment.

Now, all of those numbers come with a caveat. These are very early days, the data streams are not as robust as they need to be and we haven't yet had the first full detailed report but that's the trend. It will be rolled out, we hope, in Brighton and Blackpool very shortly. We're talking about rolling it out in Manchester and Birmingham is on the hit list. So the hope is that

across the country we will have a period where everyone in an emergency department is tested.

That will give us a cohort of patients who need treatment and care and we have strategies to look after them but it will also give us a very good idea on what we're missing.

As I mentioned at the beginning, we're getting to a law of diminishing returns. We want to make sure we're investing our resource, our people, in the right places, and what I don't know is what I don't know. Where there are the people I don't know about hiding, where are there little pockets of hepatitis C infection that I'm not hitting with our current strategies and a random testing in people turning up in emergency departments will help give us that data, and that will help inform our future strategies.

MS FRASER BUTLIN: Just to be clear, it's everyone who attends the accident and emergency and has a blood test.

PROF FOSTER: And has a blood test, exactly, yes.

MS FRASER BUTLIN: But there's no requirement for the doctor to think there's a risk factor here, it's simply a blood test and it gets ticked?

PROF FOSTER: If I go to casualty and stick my arm out, they'll test me.

MS FRASER BUTLIN: Fourthly, you've mentioned the Liverpool

surplus blood testing. What does that involve?

PROF FOSTER: So the proposal here, and we're still working our way thorough this unfortunately, is to take 17,000 blood samples that have been tested for other reasons, so blood samples from GPs, blood samples from hospitals, surplus samples in the laboratory, run those through a hepatitis C testing programme.

Again, that's looking at a population of patients that don't have any obvious risk factors and, again, it will feed into the models we're generating of where are the missing patients that we're missing. I have to say it's stumbling along a little bit at the moment, there's quite a lot of IT issues, quite a lot of laboratory capacity but I hope we can get that launched. If not, then we will have to rethink. But I think, using extra blood samples that would otherwise have been discarded to do batch runs of hepatitis C tests to give us an insight into what we're missing, is certainly a direction we want to go in.

MS FRASER BUTLIN: Then we come to the development of the case finding search tool. How will this tool operate?

PROF FOSTER: So this is a tool that we've developed in co-ordination with MSD. Again, this is one of the advantages of the pharma collaboration. They've done quite a lot of work with GP search tools looking for

patients with risk factors. We've developed a tool that allows a general practitioner to screen their patient notes and identify risk factors for hepatitis C. The plan is that we will run the tool on a GP practice, identify people at risk and then test all of those people. We want to stratify the risks and stratify the testing. So for people with a very high risk, and that will probably include people with a known blood transfusion in the at-risk periods, people with a known positive test, people with active injection drug use, et cetera, those will be contacted directly for a test by a phone call.

The people with an intermediate risk, the idea is that we will navigate them to the website and we will also, at the same time, flag the general practitioner notes, so that when they come in for an incidental event, and the third group will be people at lower risk who we will simply refer to the website.

We'd hoped that it would be up and running by now but it has been slow to implement, and what we've been working on is trying to define what are those risk categories. If we were to test a large group of people with risk factors A, B and C how many would be positive? Whilst we know from our preliminary studies that 6 to 7 per cent of GP practices, patients, flag up positive

on the algorithm -- so that would mean huge numbers of tests -- we don't want to go out and test all of those patients just for hepatitis C, a lot of them have -- the risk factor is abnormal liver function tests, so they may have other causes of liver disease and it seems silly to go and test people today for hepatitis C, go back next week when we're doing a hep B, we want to do them once. So we're looking at ways we can automate that and link into a more general liver screen.

I think we are probably going to go, if we can, to a national overview of this. Our attempts to persuade our primary care colleagues to run the tool and work with it have been disappointing, they've got a lot of pressures on at the moment. So we're working with NHS Digital and the idea is we will do this across the country. So at central office we'll go through every patient's record throughout the country, flag up those with risk factors for hepatitis C and then those will be contacted electronically or whatever.

The governance, the information rules about handling data in that way, are extraordinarily complex, and we haven't yet solved it. I think it's fair to say that we have an absolute commitment to screen GP records and pull out those patients who are at risk and, obviously, what risk factors we find will be informed by the other

studies that we're doing, the casualty studies, the look-back studies.

MS FRASER BUTLIN: You said there that one of the risk factors that would put someone into the high-risk category would be a transfusion in the relevant period.

PROF FOSTER: That's right but we're very aware that, because of the paper records at that time and the electronic transfer, that transfer may be incomplete, which is why we're looking at other markers, abnormal liver function tests and other risk factors.

It's difficult to know where to look until we've done the preliminary screens that would give us more information on the risk factors but identifying a high risk cohort is an absolute priority for us.

MS FRASER BUTLIN: You've pre-empted my question, which related to the difficulties of a lack of evidence in medical records. So, in terms of that, are you building into the risk factors at this stage anything that suggests if there's been major trauma, even though there's not a transfusion noted, that would count or perhaps evidence of the a woman having given birth in a particular time frame?

PROF FOSTER: We do -- it's a very good question and, at the moment, we don't include major trauma and we don't include previous pregnancy. Clearly, if that were to

come up as a potential flag then we would incorporate it, and I'm sure we will come on to in a moment the 100,000-patient study that again we hope will inform.

So the challenge we're trying to face is not overburdening primary care colleagues but not missing anyone and that is the tension that we're constantly running.

It's also important to bear in mind that people very quickly get fatigued if they're doing tests and not getting positive results. So we did a large scale study looking at hepatitis C in people of Pakistani heritage, and it was a research project, but very quickly GPs were saying "We've tested 100 and found nothing, this is a waste of our time", and of course that is a problem if you are looking for an uncommon condition and doing a lot of tests that come back negative.

Healthcare professionals disengage and realise that it's a waste of their time. So we need to be very careful into how we manage this, how we sell this to our primary care colleagues that it is worthwhile if they're testing a lot of people and finding very few.

So there's constant tension between investing time and resource and mission fatigue, and finding numbers of patients, and we have to try to find a way round that, and our policy at the moment is to get the data that

will allow us to have a very strategic approach to this, getting the maximum in return on our testing approach.

MS FRASER BUTLIN: I've just had a message from our stenographers asking if we could both speak a little more slowly because they are trying to take a full note of our conversation. I think we've both got so engaged with it we've forgotten about the stenographers!

PROF FOSTER: My apologies for my pace.

MS FRASER BUTLIN: In terms of engaging with your primary care colleagues, perhaps this is something we'll confirm back as a full panel, if we may, but in relation to one particular aspect, do you agree that, to some extent, the flagging approach will only work if the significance of that flag is fully understood by the GPs?

PROF FOSTER: I -- very much so. We have to work with our primary care colleagues. Primary care colleagues quite rightly say that if the 'while you're there' testing were to take place on every patient, they would spend the entire consultation going the 'while you've got the patient', do their blood pressure, their diabetes, mention the cervical screen -- sorry, I'm speeding -- but GPs are being asked to do large amounts of primary prevention and every extra test means that something else has to be reduced, and you're quite right that we have to work in partnership and we have to be sure that

we're making good use of their skills.

MS FRASER BUTLIN: What work has been done and is planned to be done to ensure that primary care colleagues are equipped to deal with patients and have that understanding of hepatitis C?

PROF FOSTER: We've had a number of focus groups with primary care colleagues, we've had a number of education sessions, we've had a number of lecture sessions -- not all of which, I have to say, have been very well attended. So our strategy going forward is to use the GP Champion model. And the reason for doing that is it's been very successful in HIV. So using GPs who believe in the value of hepatitis C testing persuade their colleagues is, we think, more likely to be successful than having myself or one of my many esteemed colleagues banging our particular drum. So we think we will subvert from within.

MS FRASER BUTLIN: The final measure you've noted is research to identify prevalence in those who wouldn't be identified by the case findings search tool. Can you tell us about that?

PROF FOSTER: So this is a programme of work we've commissioned from the University of Bristol, in Matt Hickman's group, who have done a lot of work in primary care. We will be going out to some

70-80 primary care practices, going through randomly picking patients over the age of 40 and sending them through the post an oral swab. So you wipe the inside of your mouth, send it back, and that will give a hepatitis C test result. The patient will then be contacted if they're infected, obviously, and offered treatment, and we will then look at how many of those patients would have been identified by the MSD search tool, how many would have been identified by other flags on their notes and how many would have been missed.

So the idea is to look at the unknown unknowns. We're hoping from the 100,000 that we will get at least 10,000 to 15,000 returns. We know that there's a poor return rate. I can tell you that the last meeting I had, which was a few weeks ago, we had over 10,000 samples returned. At that stage the first few thousand had been tested and a single antibody positive case had been identified and was working through. I haven't heard of any more positive cases in the remaining 5,000, so at the moment we're looking at a rate of about one per 5,000, one per 10,000 people who have no obvious risk factors. So the hope is, again, that combining that data with the emergency department data with the Liverpool 17,000 surplus samples data will give us an idea of what we're missing, because my challenge, as

I said right at the beginning, is how do I deploy the resource in the most effective way? Who am I going to miss?

I really don't want to stop the hepatitis C programme until we've got everyone who wants to be found. And we all accept there are people who do not wish to be tested and they're perfectly free to do so, and there will be people who will test positive who do not want treatment, and they're perfectly free to do so. So we need to strike the balance between pestering people and informing them. I don't want to stop too early but equally, in a very resource-stretched service, I don't want to take money away from testing for hepatitis B, where we have huge numbers of people to find, and waste my time looking for people who aren't there. So it's finding the sweet spot between an appropriate delivery of treatment and appropriate testing strategy that uses the resources widely.

As I say, it's not -- it really isn't, for once, about the money; it's about the time and the opportunities to primary care, and everything that we do for hepatitis C has an opportunity cost for something else. So we're trying to get the data to allow us to make an informed decision.

MS FRASER BUTLIN: And you've said in your -- sorry, before

we get there, once that research is complete, particularly the Bristol research and the case study -- case search tool, what do you anticipate the next steps would then be?

PROF FOSTER: I think there are three possibilities. The first is that the rate is very low, in which case we congratulate ourselves, celebrate, and think about where are the tiny pockets left. I don't think England universally has been -- is close to elimination, I think there are parts that are very close to elimination. So it may be that there is very little left to be done, and that would be very good news.

It may be there's a very large number in a particular group. And clearly if, for example, we find that, to take your pregnancy-associated transfusion group, if we find that women who gave birth 30-40 years ago have a surprisingly high risk of hepatitis C, then we could organise a targeted case-finding initiative, perhaps with a targeted publicity campaign that would pool in that particular risk group.

The third possibility is that we will find very large numbers across the board, that we're further away from elimination than we think. And if that's the case then we will need to think again about some form of near global testing. My personal view would be that that

global testing would be best delivered as part of a liver health screen. I don't really want to go and test people for hepatitis C and then go back next year and do their diabetes and their other tests of liver disease. I'd rather do a liver health screen once and make sure the patients are properly reassured.

So those are the three possible outcomes and we'll make decisions, obviously, as the data comes through.

All the data, important to say, of course, will be published. This will all be public domain data. It will be published in peer review journals. NHS England will make it available as press releases. So this will be a public consultation and, clearly, if there's a very strong feeling from the general public that we should be doing less or more, then we'd take that into account.

MS FRASER BUTLIN: In your statement you've expressed a view that there are probably not many more individuals who have been infected with hepatitis C by blood or blood products who have not yet been identified. Can you explain why that is your view?

PROF FOSTER: So several reasons underlying that. The first is I run a big clinical practice in the northeast of London and I haven't seen a patient who has been infected by blood or blood products who hasn't been diagnosed for many, many years now. And that tends to

be the view of my colleagues. So we're not seeing many people coming forward. I'm very much aware that Rachel Halford from the Hepatitis C Trust tells me they have a regular stream of phone calls, which is clearly a matter of concern. But if we look at the numbers -- the Inquiry, as you know, produced a detailed review of the likely numbers, and, if I quote, the mean number was 2,700 people chronically infected were still alive. In the English treatment database, we have 3,498 people treated --

MS FRASER BUTLIN: Could you just pause there to allow us just to put the table up from the statistics report so that people can follow the numbers.

The reference is EXPG0000049, and it's page 54 which is the table, I think, Professor Foster, you're referring to.

It's page 50 of the physical copy if anyone is using the physical book, 54 on the electronic version.

Thank you.

If we can just zoom in to the table so we can see it. There we go.

Professor Foster, you were saying?

PROF FOSTER: Um ... I'm not sure --

MS FRASER BUTLIN: You were looking at the column which is "Chronically infected, survived to end of 2019",

I think, which, at the bottom, "Total UK" gives a figure of 2,700.

PROF FOSTER: I have it. Yes, so, as you correctly say, thank you, 2,700 is the total UK estimate.

MS FRASER BUTLIN: With a range of 3,910-2,050?

PROF FOSTER: Exactly.

So there are clearly a lot of assumptions and estimates in this that the author has made very clear. What we know from the NHS England treatment registry, we ask people to record all the treatments that they administer, and there are financial penalties if they don't. So they are asked to record a risk factor of 'infected by receipt of contaminated blood or blood products'. What we don't do is distinguish whether that was administered in the UK or abroad. So there may be some increase. We also have it as patient thoughts. So it may be that patients believe they might have had a transfusion and report that as their risk factor when it fact it's different. So the data we have comes with caveats to it. But even allowing for the caveats, in England I can tell you 3,498 people, when I last looked at the registry download, which was a few months ago, had been infected in that way. So the total number of patients that we have treated in England is significantly greater than the total number estimated to

be alive within the United Kingdom.

So that gives me some degree of confidence that we are close to finding and treating all of those patients infected in that way. But as I hope I have made clear, we're not sufficiently arrogant to say we've got them all because there will always be people we miss. I think we have a reasonable strategy to try to fill the gaps, and I think all of the different studies that we've unveiled will give us confidence to say whether we are close to finding everybody or not.

MS FRASER BUTLIN: And as you've said, there's -- and the Inquiry has heard evidence from the Hepatitis C Trust in relation to, as you described, a fairly steady stream of people --

PROF FOSTER: Yes.

MS FRASER BUTLIN: -- who have recently been diagnosed with hepatitis C, and indicate that their risk factor is blood or blood products?

PROF FOSTER: I'm absolutely sure there are people out there. I'm -- tragically, we will never manage to find everybody, no matter how heard we try. The question is: how many are we missing and what is the opportunity cost of finding those people? If I put all my resources on testing everyone for hepatitis C, then other tests will not be done. And that is the challenge that we're tying

to face. How do we make best use of the human resources that we have to minimise the harm to people at large? And I'm very cognisant of our obligation to do all that we possibly can to find everyone who has been infected, whatever the mode of infection. We want them found and we want them treated.

MS FRASER BUTLIN: Is it right, then, that the search finding tool and the research by Bristol will also assist you in assessing whether there is a cohort that are being missed in terms of those infected by blood or blood products?

PROF FOSTER: Absolutely. One of the driving factors behind the Bristol study was to answer exactly that question. There are two cohorts I worry about: people who dabble with illegal drugs and have moved on in their lives and don't want to declare it, and people who are infected by blood or blood products who don't have records or indeed a memory of it. And I'm very aware that people will be infected by blood transfusions during operations when they didn't realise they'd had a transfusion. So those are the two big unknown unknowns at the moment, and we're putting a lot of effort into finding out how many fit into those different categories.

MS FRASER BUTLIN: Thank you. That table can come down.

Before I move to the others on the panel and discuss

similar questions, there are a couple of matters that arose in your statement, on different points, that I've been asked to ask you about.

In terms of the phase 1 of the strategy and the direct active anti-virals, was any consideration given to early access to those drugs for the infected blood cohort?

PROF FOSTER: We discussed this at great length and the decision we reached was that it would be inappropriate to treat patients with milder disease because of the mode of acquisition rather than patients with a more severe disease.

At that time we had very limited access to the treatments. There was a fixed number of treatments. We had a large number of people with advanced liver disease who were likely to die and our initial priority was to treat people who were likely to die within the next 12 months. We then extended to people who were at significant risk of harm, patients with cirrhosis, patients with significant mental health problems from hepatitis C, and we recognised at the beginning that some people with hepatitis C have their lives ruined by the mere presence of the infection and they will not be able to move on with their lives until they've cleared the infection. And we recognised that that was a reason

for prioritising patients. We recognised that mothers who were wanting to get pregnant may well want to be clear of the virus, so we allowed that to be a priority.

So we tried to cover all possibilities. We were specifically asked whether or not we would consider prioritising patients by mode of acquisition and we decided that, given the National Health Service has never prioritised any treatment by mode of acquisition, given that it would be inappropriate to treat people with mild disease, whilst people at risk of dying were left untreated, we felt that was inappropriate. So we chose not to do so and that was our very strong clinical recommendation from the panel that was operational at the time, and that was a universal decision.

MS FRASER BUTLIN: Slightly different topic. You said in your statement that there should be universally available FibroScan technology as part of the operational delivery networks. In oral evidence, the Hepatitis Expert Group decided access to FibroScan technology as "patchy". What's your understanding of the situation?

PROF FOSTER: When we started the networks, we made available to every network funding for a FibroScan so every network had a FibroScan provided. The demand and supply has increased dramatically. I think the supply

of FibroScans as a tool is, as you quite rightly say, "patchy", but I believe there are sufficient alternatives to FibroScan that are now available. So, for example, there are blood tests there's a simple APRI scoring system that gives a very good indication of whether patients have cirrhosis, there is an enhanced liver function test, an ELF test that can be tested, so there are blood tests that can be used to exclude cirrhosis.

So whilst I agree that FibroScanning is not as widely available as perhaps I would like, I think there are sufficient modalities of investigation to exclude cirrhosis in patients and I think those are sufficiently widespread.

I think it would be very unusual for a patient not to have an opportunity to have some form of liver fibrosis assessment.

MS FRASER BUTLIN: Now this is a question you may not be able to assist us with but I've been asked to ask you. In terms of further research, do you think there is a need for further work to be undertaken on the needs of those infected by blood and blood products, particularly in terms of the longer term impacts of treatments they've received in the past?

PROF FOSTER: I've a longstanding concern about the

long-term impact of interferon-based treatments on individuals, published some research looking at its impact on psychological health. So I think I have to answer that, yes, there is a need to look at the long term impact of interferon on the other treatments. We know some of the first generation oral anti-virals, telaprevir and simeprevir were particularly toxic drugs, so I would certainly agree there is a need for evidence to assess the long-term impact of those.

I think we still do not genuinely know the lifetime impact of hepatitis C infection because, fortunately, not too many people have died from it, and there may well be other consequences that will manifest in the distant future, as a result of those treatments that we deployed, so I think it's certainly a reasonable research proposal.

I don't, I have to say, have any evidence at the moment that we are seeing any long term effects of interferon, telaprevir and simeprevir but it would be perfectly reasonable to look into it.

MS FRASER BUTLIN: Thank you.

Professor Dillon, you're a consultant hepatologist and gastroenterologist with NHS Tayside and also the clinical lead for hepatitis C for them.

PROF DILLON: Yes.

MS FRASER BUTLIN: You're attending today on behalf of the Scottish Health Boards.

PROF DILLON: I am.

MS FRASER BUTLIN: What can you tell us about your involvement in the hepatitis C work in Scotland?

PROF DILLON: So since 2009, Scotland -- each Health Board has been mandated by the Scottish Government to have a clinical lead for hepatitis and I've been NHS Tayside's clinical lead. The clinical leads for those health boards meet together two or three times a year to discuss strategic policy across hepatitis C, and to respond to whatever diktats we receive from the Department of Health in Scotland as to what we should be doing, so that process and that structure has continued since then.

MS FRASER BUTLIN: In 2006, the hepatitis C action plan phase 1 in Scotland was implemented **(The witness nodded)** and in 2008 phase 2 was implemented.

(The witness nodded)

Could we just turn to WITN4062002, please. This is the proposal approved by the Scottish Government in July 2019, the Action Plan: Achievements ... and Proposals. If we turn to page 3, please, Lawrence. We see in 2008, just at the bottom of the page, there's a timeline, and in 2008 it indicates that there was

serious investment, approximately £15 million per year of additional dedicated funding for education, awareness raising, prevention, diagnosis, treatment/care services and for co-ordination, monitoring and research and the introduction of hepatitis C treatment targets.

What can you tell us about that block of funding that was started in 2008?

PROF DILLON: So that was distributed to each health board to fund additional staff and resources and treatment costs to start to increase the numbers of patients being treated for hepatitis C using interferon based regimes. So each health board made its own decisions as to what it should do. It was mandated to have an executive lead on the board responsible for hepatitis C and a clinical lead and it led to the funding of several nursing posts in each health board to allow and facilitate treatment for hepatitis C and pay for those treatment costs. And FibroScan machines, as Professor Foster has alluded to already became part of that development as well in terms of being able to stage patients in terms of, in those days, treating patients with cirrhosis, with interferon based therapies was somewhat risky.

So rather than prioritising patients for treatment we were finding the patients we couldn't treat with those investments. So that was that money. Some of it

was recurring and has become part of the each health board's infrastructure.

MS FRASER BUTLIN: In terms of identifying those who were at risk of being infected with hepatitis C, finding the patients, what work took place at that point?

PROF DILLON: At that point, there was rolling out of dried blood spot testing to make testing easier, so instead of having to take venipuncture blood, a drop of blood from a finger spot could be used to make the diagnosis of hepatitis C, it was sent to the lab and processed in the usual way. But it meant people were much closer to a test in terms of, rather than having to find someone who could do venipuncture, we trained large numbers of people who could do dry blood spot testing in the environment where the person who was at risk was located.

There were a series of look-back exercises conducted at that stage around blood transfusion, awareness raising amongst general practice, sign guidelines were developed recommending who should be tested and listing the risk factors at that stage, and those were promulgated through joint meetings with general practitioner colleagues, other general medical colleagues and generally trying to raise awareness around hepatitis C and use that opportunistic testing.

It also -- the action plan also took over the previously research-based database across Scotland for hepatitis C, which gave us everyone who'd ever had a positive diagnosis of hepatitis C in Scotland, and so their healthcare records could be followed and the health boards were then aware of who was in their territory and who they had to be responsible for.

We've never had the overarching strategies of England, each health board has made its own decisions, we don't have an NHS England equivalent in Scotland, and so each health board makes it decisions. Now, clearly we have a geographical issue in Scotland, we have 14 health boards, four of them are large urban-based territories, three are medium size with some significant conurbations in them but lots of rural things, and seven are very rural with a very, very different complexion. So hepatitis C poses different challenges in each of those environments.

MS FRASER BUTLIN: If we turn the page and continue the timeline, we can see there the questions of the Penrose Report and its recommendations and then, in 2019, the Scottish Government launches its Hepatitis C Elimination Strategy. If we turn the page, we have some data. Achievements include:

"Between 2006 and 2018:

"A 45% reduction in the number of people living with chronic hepatitis C from an estimated 38,000 to 21,000.

"A 55% reduction in the number of people unaware of their infection from 23,500 to 10,500", and then a figure in relation to those who have cleared their virus.

Then, in the context of the era of the direct acting anti-viral therapies available since 2014:

"New presentations of hepatitis C related decompensated cirrhosis (liver failure) declining 67% from a peak of 141 in 2013 to 47 in 2018.

"New presentations of hepatitis C related hepatocellular carcinoma declining 69% from a peak of 58 in 2016 to 18 in 2018.

"Hepatitis C related deaths declining 49% from a peak of 67 in 2015 to 34 in 2018."

There is then the strategy proposed that's dealt with --

Sorry, sir, it's just been indicated to me that the Northern Irish link appears to have just gone down. We've lost Dr McClean.

SIR BRIAN LANGSTAFF: Yes, I don't know if that's got anything to do with putting the document up on screen, but --

MS FRASER BUTLIN: I wonder if we should just pause for

a moment and establish whether Dr McClean can hear us at least.

SIR BRIAN LANGSTAFF: We're pretty close to when we would normally have a break.

MS FRASER BUTLIN: We are.

SIR BRIAN LANGSTAFF: So perhaps this would be -- albeit forced upon us -- an earlier break.

MS FRASER BUTLIN: Absolutely, sir. Was going to deal with the document and then suggest a break but perhaps we can take a break now instead.

SIR BRIAN LANGSTAFF: Let's do that and then come back to the document. So we'll take a break now until 11.40 and hope that when we come back we will have full function from Northern Ireland restored.

(11.11 am)

(A short break)

(11.40 am)

SIR BRIAN LANGSTAFF: Yes.

MS FRASER BUTLIN: Thank you, sir.

We were looking, Professor Dillon, at the 2019 Action Plan: Achievables and Proposals, and we had just looked at the achievements between 2006 and 2018, and then since 2014.

We can see then the heading "The Following Strategy is Proposed", with a "Vision" and a "Why".

Then if we turn the page, we pick up "How":

"NHS Boards, together with local authorities and third sector organisations, and supported by Health Protection Scotland, should:

"- Treat a minimum of 2,500 people during 2019-20 and 3,000 each year thereafter; it is predicted that this strategy will achieve elimination by 2024.

"- Guided by the recommendations by the SLWG on Hepatitis C Case Finding and Access to Care, intensify efforts to identify those people undiagnosed, and to re-engage diagnosed people not in contact with hepatitis C services. An eclectic model of hepatitis C care -- ie, the provision of services in both hospital and community settings, tailored to the needs of the patient -- should be adopted."

Then there's a point about those who inject drugs.

You said earlier, Professor Dillon, that it's a matter for local health boards to deal with this strategy.

PROF DILLON: Indeed, so each health board has its proportion. Up until 2019, the proportion of the treatment target was by population, and so each health board in proportion to population had to contribute to that total target. So the 2019/2020 target of 2,500 was achieved, but there were some health boards that did

better than others, and so Greater Glasgow and Clyde and Tayside were particularly overdelivering in terms of therapy.

We don't have the same pharma arrangements as NHS England does but we did have a capped deal so that as we reached a certain number of patients treated, the drug effectively became free beyond that; so if you over-treated in any one year there wasn't a financial penalty. We didn't get financial rewards for treating more patients but it didn't cost us any more. So there was an incentive to try to reach that treatment target so you could then treat patients that you wouldn't have to treat in future years.

So the 2,500 was achieved, and then we all know what happened in 2020.

The Short Life Working Group did meet and did convene and did finish its recommendations, and so that produced a series of -- a review of the world literature as to what was the best pathways of care to be used. It highlighted the work done in various parts of Scotland, so what was being done -- what was excellent in parts of Scotland were shared. We looked at our English and Welsh colleagues as well to see what they had and we shamelessly borrowed ideas from them.

So that potpourri of ideas, of ways of reaching the

various risk groups were identified, and each health board could then take what it needed to allow it to achieve its targets. Clearly the bigger urban health boards had a different set of risk factors in terms of injecting drug use being a much more dominant risk factor than in other parts of the country. And so that was the -- that's why the word "eclectic" was used.

MS FRASER BUTLIN: Can you give us a flavour of the sorts of measures that local health boards have taken in order to identify people?

PROF DILLON: Okay. So, in terms of diagnosis, we've -- so in all addiction centres that are NHS provided, which is the majority model in Scotland, it was a requirement that everyone who was on opiate substitution therapy was tested every year for hepatitis C. Treatment pathways and diagnostic pathways were rolled out into needle exchange facilities and so using dry blood spot testing to ensure that patients could provide, could get easy access to testing.

There was ongoing awareness raising amongst general practices around what the risk factors were. There was automated testing of abnormal liver function tests. This was for all liver diseases but included hepatitis C and hepatitis B testing. This is now standard practice across NHS Tayside and NHS Fife, which accounts for

800,000 people of our 5,100,000 population.

NHS Glasgow and NHS Lothian, which are 1.5 million and 800,000 respectively, are about to roll this out. It has been Government policy but clearly the last two years have rather held back some of these sorts of developments.

MS FRASER BUTLIN: And have there been any general awareness campaigns about hepatitis C, run by local health boards?

PROF DILLON: So there have been over the years since the action plan started. There have been none since the elimination plan was decided. The individualised treatment targets for each health board based on -- as well as on their population -- on their previous performance, were being developed for roll-out in the 2020/2021 financial year. All of the staff that were involved in that disease modelling had another disease to model instead, and they have only just come back to hepatitis C work about six weeks ago.

I'm promised in two weeks' time at a meeting that the first tranche of those new numbers will be available to us so and so we will have some more data at that stage.

MS FRASER BUTLIN: At this point the elimination programme doesn't have any specific measures addressing the identification of people with hepatitis C infected

through blood and blood products; is that right?
PROF DILLON: It doesn't, no.
MS FRASER BUTLIN: Can you explain for us why that is?
PROF DILLON: So we looked back through our previous efforts to see if there were any gaps, anything that we couldn't do, that we could do anew in terms of reviewing GP records, in terms of looking up blood transfusion records, in terms of look-back procedures, et cetera. All of those have -- where they are feasible, have been done already. We looked at our database in terms of -- because of Scotland's its record linkage abilities, we've captured everyone that's ever had a hepatitis C diagnosis in Scotland. And as of the end of 2020, which is -- I think the numbers are for your statistics, we have diagnosed and treated 460 people, who are still resident and alive in Scotland, which is in excess of the proportion of patients from the UK estimates that you would expect. So, rather like Professor Foster has alluded to already, we seem to have found more people than the estimates would suggest that have blood products or blood transfusions as a risk factor, which gives us some confidence that the numbers of patients who could be missed will be relatively small.
MS FRASER BUTLIN: What do you see as the barriers in Scotland to identifying any remaining people who have

been infected by blood and blood products?
PROF DILLON: So if we go back through the record, so clearly the patients who have had haemophilia or an inherited bleeding disorder are likely to be under ongoing follow-up and will have been in contact with their haemophilia centres or bleeding centres and will have been tested. Those that had random blood transfusions are the more challenging group to find. If we -- we've looked back at the transfusion books that go back into the 1970s and '60s and these are old-fashioned large ledgers. Most of them contain a date, a name with no date of birth, and a ward on which the patient might have been on at the time that the blood transfusion was requested.

We know that the blood left the transfusion laboratory with that patient's name on it. We have no idea if the blood was ever transfused or not, and clearly, with, you know, some common surnames, et cetera it's difficult to identify who that patient may have been.

The hospital records, going back and doing name searches for someone who might have been in hospital at that time, have been destroyed, by and large, so that's a problem.

In terms of hospital discharge summaries that in

days of old would have been in the old Lloyd George envelopes that occupy -- you know, took up lots of space in GPs surgeries, those were summarised in preparation for digitisation in the mid-1990s and so, if we had a discharge summary of three pages summarising a complicated gallbladder operation to remove the gallbladder that went wrong and had multiple blood transfusions, if the patient came out the other side of that, that large discharge summary would be summarised as cholecystectomy, which is a surgical term for gallbladder removal, and any other details about blood transfusion, et cetera, will have been lost in that digitisation. So that's one of the problems.

More recently, we have been -- so there has been national guidance that any blood transfusion carried out in hospital should appear in discharge summaries. We've audited that across Scotland and, at the moment, we get about 50 per cent of blood transfusions recorded in a discharge summary. So, in terms of trying to find those patients, you can see that we sort of progressively miss people.

Assuming there are relatively few left, the transfusion booklets are no use to us. The discharge summaries have been lost from hospital records back in that period of time because they've been culled, unless

the patients have ongoing contact with the hospitals, in which case they're very likely to have been tested. The GP records are lost to us now and we don't have that option, and, you know, if the rate of recording of that data in the GP records or in the discharge summary is not very good now, when it's mandated, we can only assume it was worse in the past.
MS FRASER BUTLIN: In terms of the elimination strategy going forward, what measures do you understand local health boards to be taking to identify people who were infected with hepatitis C generally, that might also pick up those who have been infected by blood or blood products?
PROF DILLON: So the risk factors that are identified will still be there and are still operating since 2009 and those are being -- that message is being re-emphasised.

There is a move across Scotland for the earlier diagnosis of liver disease in general, and we are, as the -- the process of -- a device called "intelligent Liver Function Testing", where, if blood is sent to the lab for liver function tests, if they are abnormal, a whole gamut of tests are performed to arrive at a diagnosis for the liver disease and amongst those tests are hepatitis C and hepatitis B.

That's now Government policy, clearly the rollout

has been held back by Covid. It is active in the two health boards, which I think I mentioned before, and it's being rolled out across the country. So that would help detect those patients who have -- their risk factor for hepatitis C is lost in the past and are of advancing years, and you can find patients that way.

In Tayside we've now put 21,000 patients through that process in the years that the service has been running and we've found 142 hepatitis C positive antibodies. To my recollection, none of them are transfusion related and all of them have other risk factors or are idiopathic.

MS FRASER BUTLIN: As I did with Professor Foster, there is one other matter in your statement I've been asked to address with you. You address in your statement palliative care and say that the viral hepatitis contribution to the group of patients requiring palliative care is very small. Can you explain for us what you meant by that?

PROF DILLON: Okay, palliative care in liver disease is an emerging need. Hepatologists have been rather focused on saving everybody and resurrecting everybody from their lived failure because that's our background. We are now becoming increasingly aware of a group of patients in whom we can't achieve cure and survival and

they are not suitable for transplantation and so we need to be more focused on their symptomatology.

Palliative care medicine is also changing and is moving away from patients who will inevitably die of cancer to looking at symptom control in a broader group of patients, and liver disease is one of those areas where there's a high mortality and lots of symptoms that can be controlled.

That's need around liver disease as a whole and that's a growing area of need. There are emerging professional consensuses as to what should be done, at the moment there's no Government funding to support that. Within that group of patients, it depends on the etiology of the liver disease, if you can't change the projection or trajectory of the liver disease because you can't change the underlying cause then the patients will inevitably get worse.

In viral hepatitis, both hepatitis C and hepatitis B, treatment well change that trajectory for most patients and so their liver will recover and regenerate. So, if we were making the case for palliative care and the needs for it, the hepatitis C group of patients contributes less to that overall need because they have the option for cure, as we've seen, for instance in the numbers of patients being

transplanted for hepatitis C, which has, from -- in 2011 and 2012, we were predicting that our entire transplant programme in Scotland and the UK would be overwhelmed by hepatitis C and we would be transplanting nothing but hepatitis C, and I think most transplant units can't remember the last time they transplanted someone for hepatitis C induced liver failure.

There is still an ongoing need for hepatocellular carcinoma transplantation, there is still a need for palliative care around those long term hepatocellular carcinomas but there is emerging evidence that the risk of hepatocellular carcinoma falls over time after cure. It probably never goes back to population normal but the risk isn't as high as when you have active infection. And that's my reason for saying that the driving force for palliative care is not viral hepatitis alone; it's the generality of liver disease.

MS FRASER BUTLIN: The Inquiry has heard evidence from the palliative care panel that, from their experience, it wasn't a historical thing. One of the experts indicated:

"This is seeing patients within the last few weeks of my practice who are presenting with advantage liver disease from blood transfusions years ago. It's still an active issue and these issues are still very live."

Does that then not accurate with your experience?

PROF DILLON: So if you'd come to my ward five years ago, six years ago, half my liver patients would have had hepatitis C. The only patients we have in who have had previous hepatitis C are now in because of hepatocellular carcinoma, and that's a small number. So there has been a dramatic change in the complexion of the people that we're seeing in liver failure on the wards.

And I think it's important to differentiate those patients who have active viraemia and those who had hepatitis C and have an additional risk factor that's driving their liver disease, be it non-alcoholic fatty liver disease or alcohol-related liver disease, that the two together are acting synergistically to drive things forward. So the previous damage from the hepatitis C has fertilised the field, if you like, and then the addition of another liver disease drives them through faster.

MS FRASER BUTLIN: So you are seeing that element where there's a synergy between the previous hepatitis C, even though they're now in sustainable virological response but the synergy of that previous issue and something else --

PROF DILLON: Yes.

MS FRASER BUTLIN: -- does drive the liver disease more rapidly?

PROF DILLON: Yes.

MS FRASER BUTLIN: Thank you.

Dr Healy, you are the blood-borne virus clinical lead for Wales; is that right?

DR HEALY: Correct yes.

MS FRASER BUTLIN: Can you tell us what that role involves?

DR HEALY: Yeah, so, similar to my colleagues, it's my responsibility to look at the clinical side of hepatitis C management and hepatitis B management and elimination. So I help with strategy around testing and treatment across the health boards in Wales. I lead a network of clinicians across Wales, similarly to try to drive towards elimination. Yeah, and I'm charged, I suppose, on a clinical basis, to try to find as many patients and deliver treatment and a cure to as many patients as possible.

MS FRASER BUTLIN: Could we turn to RLIT0001821, please.

This is a Welsh Health Circular from October 2017. We can see it's title "Attaining the WHO targets for eliminating hepatitis (B and C) as a significant threat to public health". If we go towards the bottom of the page we can see it's been sent by the Chief Medical Officer for Wales.

If we just turn the page, Dr Healy, I'm just going to take us through the document and then ask you about it:

"The WHO has announced a global sector strategy on viral hepatitis which sets out to eliminate hepatitis B and hepatitis C as significant public health threats by 2030. The WHO target is a 90% reduction in incidence and 65% reduction in mortality due to hepatitis B & C by 2030. Wales is signed up to this strategy.

"The Minister for Social Services and Public Health has been advised by The Welsh Viral Hepatitis Subgroup of the Liver Disease Implementation Group on what is required from the NHS and partners for Wales to achieve this target."

Then if we could go down to the second half of the page:

"I am writing to you to request that measures are put in place to:

"Reduce and ultimately prevent ongoing transmission of [hepatitis C] within Wales;

"Identify individuals who are currently infected with [hepatitis C] including those who have acquired [hepatitis C] outside the UK and are now resident in Wales; and

"Test and treat individuals currently infected with

[hepatitis C] who are actively engaged in behaviours likely to lead to further transmission."

Then if we turn the page, please, we see a heading, "Identify individuals who are infected with [hepatitis C] including those who have acquired [hepatitis C] outside the UK and are now resident":

"2.1 Individuals infected with hepatitis C who were not linked to care.

"There are a number of individuals who have been diagnosed with hepatitis C but who, for a variety of different reasons, have never been linked to care or who have never received follow up investigation or treatment (for example, if they were diagnosed before there was any treatment available) who now can be identified through searches of the laboratory data system ...

"By the end of December 2017 Public Health Wales will have sufficient information collated from laboratory systems to identify these individuals and will notify general practitioners of affected patients registered with their practice."

Just pausing there, what can you tell us about that process of identifying individuals who had a positive hepatitis C test but hadn't engaged with treatment?

DR HEALY: Yes, so that programme of work is ongoing. It was separated out into two phases. The patients

identified -- it's 5,000 there but I think it was 8,000 in total with the final figure -- vary in their risk, in terms of having ongoing hepatitis C. So this is been established by a trawl through our testing databases, our lab databases.

So sometimes we can establish someone has active infection and hasn't been treated. Sometimes we can only establish that someone has been tested and it's not clear whether they've been treated or not. So they're in different categories of risk.

In the first phase, 1,650 individuals were written to alert them of their potential risk. So that's the highest risk group in terms of having ongoing infection. We had 140 individuals, about 10 per cent of individuals, who responded to that and 62 who have completed treatment as a consequence.

Phase 2 was interrupted by the Covid pandemic and we're now just in the process of starting phase 2.

Of those remaining 90 per cent that didn't respond to a letter, their details, along with details of other patients on that list, will be passed to the blood-borne virus teams across Wales, and it will the responsibility of those teams to cross-check against patients that have been treated. So some of these individuals will have actually been successfully treated and they're just not

linked up on the database, to actively try to contact them to bring them back to service, but also to flag them, so that if they make contact with services for other reasons, that the issue of hepatitis C can be picked up.

When we wrote to the GPs to alert them of the patients involved, we also asked for them to be flagged on the system for that reason as well, so that they could be picked up in that way.

MS FRASER BUTLIN: Again, this may be something you can't assist us with but do you have any sense of the numbers of those patients who simply couldn't be tracked because records aren't there, their address is wrong, someone has changed their name, those sorts of issues?

DR HEALY: I could get figures on that. But of the 1,650 that we wrote to, they will have been matched across the -- I think it's called the Welsh Demographic Service, so they have been matched and they have addresses that could be written to. So those 1,650 are the ones we know we can contact. But there will be some that aren't contactable, for sure.

MS FRASER BUTLIN: And in terms of those who are not the 1,650, what's happening for those other individuals?

DR HEALY: Yes, so that's part of phase 2, where we're trying to match them up with local teams to see if some

have been contacted.

They don't always contain the full dataset for example. So if they don't have an NHS number or they don't have a full demographic, sometimes there might be spelling mistakes within the system, et cetera, et cetera, and they can only really be overcome by individuals looking at them and sort of intelligently working them through.

MS FRASER BUTLIN: And that will be the responsibility of the blood-borne virus teams --

DR HEALY: Yes.

MS FRASER BUTLIN: -- within the region you think the person is to then try to actually track down the correct individual?

DR HEALY: Yes, exactly.

MS FRASER BUTLIN: If we continue reading the document we see 2.2:

"Identifying individuals who are infected with hepatitis C, who have never been tested and are unaware of their infection.

"[Hepatitis C] testing on the basis of risk exposure rather than clinical diagnosis of symptomatic presentation is currently available via substance misuse services, GUM services, prisons and in some primary care settings throughout Wales. Despite efforts over the

last decade to improve the coverage of testing, diagnostic rates remain low and many individuals who are hepatitis C positive are unaware of their status."

"- Testing needs to be increased in all of the above settings and health boards will want to consider whether there is merit in adopting opt-out testing in substance misuse services. As a minimum, commissioners of these services should include a requirement to adhere to the existing annual testing offer for those accessing these services."

There's then discussion in relation to other -- services in relation to high prevalence populations.

And then:

"- All health boards should consider which populations are most at risk in their area and work with substance misuse Area Planning Boards ... and services, third sector agencies, [blood-borne virus] leads and blood-borne virus nurses to implement effective testing strategies.

"The Welsh Viral Hepatitis Subgroup of the Liver Disease Implementation Group is currently undertaking a number of pilots in different community settings and will share strategies which are effective."

In terms of those broader measures of identifying those who don't know that they're infected, first of

all, who has responsibility for implementing these measures in Wales?

DR HEALY: It's the health boards and the area planning boards.

MS FRASER BUTLIN: So where does the funding come from to address any initiatives that they might want to pursue?

DR HEALY: That has to come from the individual health boards and the area planning boards.

MS FRASER BUTLIN: So is it right that there's no central ringfenced funding for elimination?

DR HEALY: That's correct, yeah.

MS FRASER BUTLIN: In your statement you've talked about two other locations that funding can be obtained from. Firstly, the Liver Disease Implementation Group. What can you tell us about the funding that that group can provide -- has access to?

DR HEALY: Yeah, so the Liver Disease Implementation Group has a budget of 1 million per year. It's only ever been available on a yearly basis, so it's never been clear whether there would be another programme the following year, which means any money that was available had to be spent within that financial year. And from that money we have funded a number of posts, which are in the report, to help with elimination. So I receive one session as blood-borne virus lead. We have a national

pharmacy post, a national project lead.
MS FRASER BUTLIN: So, just to be clear, you have one session a week as the clinical lead on this?
DR HEALY: Correct.
MS FRASER BUTLIN: And one session is just half a day?
DR HEALY: Half a day, correct, yeah.
MS FRASER BUTLIN: And in terms of the funding only being available a year at a time, what impact does that have on the strategies that you could hope to pursue?
DR HEALY: Um, it significantly limits what you're able to achieve, because in general you'd find out that funding is available around about the beginning of the financial year, so any strategies that you have that you might want to implement, they then require being worked up into a business case, so you lose a lot of the time just in the preparation. So, in reality, you're only able to fund things that might run for six months, maybe even shorter, and it's very difficult to plan over the longer term.
MS FRASER BUTLIN: Would that also have an impact on the staff who you could employ, because their posts would only be secure for a year?
DR HEALY: Yeah. Yeah, so staffing you have to -- you tend to employ on a secondment basis. Although I should point out that, as we discussed at the beginning, the

responsibility lies with the health board and the area planning board, so longer-term appointments could be applied for through those routes.
MS FRASER BUTLIN: You've also indicated that some funding is available through the Public Health Wales Communicable Disease Surveillance Centre, or at least they can assist with the strategy. **(The witness nodded)**
What's their role in the elimination strategy?
DR HEALY: It's the latter, they support through programmes of work and -- within their budget. So, similar to the health board being responsible for delivering elimination locally, Public Health Wales assist through their programmes of work.
MS FRASER BUTLIN: And I think you've indicated that that's primarily through epidemiological support or data analysis and co-ordination support?
DR HEALY: Correct.
MS FRASER BUTLIN: A strategy based on long-term central funding was proposed in 2015/2016 by the Health, Social Care and Sport Committee of the Welsh Government.
(The witness nodded)
The Welsh Government report in response did not pursue that; is that right?
DR HEALY: That's correct, yeah.
MS FRASER BUTLIN: Could we just turn to that so those

watching are aware of it.
RLIT0001822.
We have a:
"Written response by the Welsh Government to the report ... on progress towards achieving Hepatitis C elimination in Wales."
And if we turn the page, we see:
"Recommendation 1. We recommend [so that's the committee recommendation] that the Welsh Government produces a comprehensive national elimination strategy for hepatitis C, with clear ambitious targets, and workforce planning built in, and provides sustainable funding until elimination is achieved. This must be done as a matter of urgency, given that the current plan will end in that year, and funding for dedicated posts is only confirmed until 2021."
And we see that the response is "Accept in principle", but then if we go down to the bottom of the page we see in bold:
"Financial implications: None. Delivering the local actions required to achieve elimination of hepatitis B and C as a public health threat will be absorbed from within existing programme budgets and NHS allocations."
So is that right? There was a proposal that there

would be sustainable central funding and the response was it would be dealt with locally?
DR HEALY: Yeah, I think that's correct. So I think their position was that they didn't have central funding for other disease targets, you know, cancer, et cetera, and that it was devolved to health boards, and they were taking a consistent approach, I suppose.
MS FRASER BUTLIN: And we see a similar point in recommendation 2, over the page, the recommendation was for:
"The strategy must include a targeted awareness raising campaign to reach out to at risk communities and also provide for education and training for health professionals.
"... Accept in principle."
But then, in relation to "Financial Implications":
"None. Delivering the local actions required to achieve elimination ... will be absorbed from within existing programme budgets and NHS allocations".
In terms of the strategies taken by local health boards, what can you tell us about what has been done by local health boards?
DR HEALY: Yeah, so similar to what's happened in England when Professor Foster was talking at the beginning, right back in the beginning when the DAAs became

available -- sorry, the directly acting anti-viral agents became available -- we had a number of people in care who needed treatment, and the treatment was allocated to those individuals on the basis of clinical need, and that backlog was cleared within 2 years. So I think -- was it -- 2014 was year 1, so by 2016 we had cleared the backlog of patients that needed treatment.

There were some anxieties, as you pointed out earlier, about people having to wait, but the wait for individuals who had mild liver disease was much shorter than anticipated and we didn't see that really as a significant clinical problem. And we worked as a network to ensure that there was equitable and transparent access to care across the country. So there was no postcode prescribing; everybody was treated at the same rate at the same time.

We worked with our haematology and consultants and teams looking after haemophilia patients to make sure that they were reviewed so that any were referred -- any that wanted to be referred were referred to care, and the new treatment options were discussed with them.

Subsequent to that, in phase 2 we have focused a lot on the -- our population where there's ongoing risk of active transmission and where we have our highest prevalence, so through substance misuse services, people

who inject drugs, we've developed key performance indicators for those services, which were due to start in 2019, again have been disrupted by the pandemic. So the target for this year is the same as 2019's target, which is 50 per cent, with an anticipation increase to 90 per cent from next year.

Treatment is freely available. Clinicians are free to choose whichever medication they feel is most appropriate for the patient that they're seeing, and we've done educational events across the country to inform primary care -- other services about the change in treatment that's available to encourage referral through to service.

We have done a number of different projects. So Professor Foster was talking about the GP programme which can pick out people with risk factors for hepatitis C., so we did trial that in North Wales some time ago. We didn't find it as successful as we might have hoped. We're watching very carefully what's happening in England, and we have been talking recently about whether that is something that we might try again, because I understand it's been quite refined since we first used it.

MS FRASER BUTLIN: Just pausing there, can you tell us what the problem was when you first used the tool?

DR HEALY: Identifying a very large number of individuals many of whom weren't at risk, and then not getting very much in terms of pull-through from primary care in relation to those number of patients identified.

MS FRASER BUTLIN: So when you say "pull-through from primary care", what do you mean by that?

DR HEALY: So we might identify a large list of people who might have a risk factor -- difficult, then, to know exactly what that risk factor is -- and then not many of them accessing testing and then not many of them ending up in treatment.

MS FRASER BUTLIN: You talked a moment ago about doing some sort of awareness raising with primary care colleagues about the new treatments. What can you tell us of what that involved?

DR HEALY: So that will have been done locally in each health board. I'm also the lead for hepatitis in Cardiff, so all primary care physicians have to go to training days and they're split so that the practices are still active. Yeah. So, in order to cover all of the primary care practitioners in Cardiff, you have to do two events. So we've done that on two separate occasions to raise the issue of hepatitis specifically with -- with our primary care colleagues.

MS FRASER BUTLIN: Have there been any measures taken

specifically to try to identify those who have been infected through blood or blood products?

DR HEALY: Not outwith those two programmes that I mentioned. So we anticipate that a significant number of people who would have been infected through blood or blood products will have been diagnosed previously. So the programme of work trying to find people who have been diagnosed but not linked to care will capture them. The primary care looking for people with liver disease, was an attempt to try and capture those individuals suffering from the same problems that we've heard from my two colleagues, in terms of what data is held in primary care and records dating back that far in relation to blood transfusion.

So that was an attempt to do that but, like I say, because of its lack of success, we've paused on that.

MS FRASER BUTLIN: You talk in your statement about a number of places that testing is available in the community. You've highlighted it being available through substance misuse services, criminal justice services, prisons and homeless services, as well as primary and secondary care, and you have said that testing in pharmacies is under development. What can you tell us about that?

DR HEALY: So because we have a rural community, we know that a significant number of our at-risk population,

people who inject drugs, only access needle exchange and opiate substitution therapy through pharmacy. So it's a key part of our strategy that testing is available in those settings.

We have found it difficult to get traction in terms of numbers of individuals being tested, so we're continuing to work on that. We're not giving up on that strategy because it's such a key element of delivering elimination because of the rural nature of Wales and the fact that such a significant proportion of people only access care that way.

MS FRASER BUTLIN: I've been asked to ask do you think that having to attend somewhere like a substance misuse centre might put people off attending for testing, particularly if they think they've been infected through blood or blood products and what do you then see as the benefits of the pharmacy provision?

DR HEALY: Yeah, so pharmacy provision is specifically targeting that group. We wouldn't expect to capture people who have been infected through other routes through that programme of work. Testing is widely available, primary care, anyone should be able to access testing in Wales in a relatively straightforward fashion.

We have also been looking at the programme of work

that was going on in England around postal testing and that's something we're also keen to develop. We want to make testing as freely available and as tailored to the individual as we possibly can, but that work is also in its infancy.

MS FRASER BUTLIN: So just to be clear the pharmacy testing is connected with needle exchange.

(The witness nodded)

It's not a general provision where somebody could think that they wanted to be tested and go in and be tested?

DR HEALY: Correct, yeah.

MS FRASER BUTLIN: So somebody who thought they might have been infected through blood and blood products would have to go to their GP to access testing?

DR HEALY: Yeah.

MS FRASER BUTLIN: Thank you.

Dr McClean. Can you see and hear me?

DR McCLEAN: Yes, I can. Thank you, Sarah.

MS FRASER BUTLIN: You are the Director of Public Health in the Public Health Agency in Northern Ireland; is that right?

DR McCLEAN: That's correct. I've been the Director of Public Health in the Public Health Agency since the 1 September this year, so relatively new in post, and in

that role, I've responsibility for ensuring that the agency discharges it's -- all statutory public health functions, so those related to infectious diseases are one area, and I'm also responsible for public health input to service development to screening and to wider health improvement activity.

MS FRASER BUTLIN: The hepatitis C elimination plan phase 1 was published in January 2021 **(the witness nodded)** so before you became director.

DR McCLEAN: Yes.

MS FRASER BUTLIN: What can you tell us of the focus of that plan? What has the focus been?

DR McCLEAN: As you say, it was published in January 2021 and it's very much focused on people who have acquired hepatitis C through injecting drugs. That is, by some distance, our biggest group of new infections, and it's a particularly challenging group to target and to engage with services to ensure we -- that people receive treatment. So, for that reason, because it is our biggest epidemiological group, the focus has been on that group to date.

MS FRASER BUTLIN: If we turn to RLIT0001696, please, Lawrence.

We see the Elimination Plan and if we turn to page 8, we see the heading "Priority populations" and

it's the second paragraph:

"Over two thirds of those treated for hepatitis C infection in Northern Ireland have a history of injecting drug use ..."

Then it continues:

"This population is a priority in terms of the clear burden of experiencing hepatitis C infection. Within this population, priority risk factors include homelessness, addictions, and admission to prison."

Then it says:

"Other populations include: people who were infected with blood/blood products, healthcare staff with needle stick injuries", et cetera.

DR McCLEAN: Yeah.

MS FRASER BUTLIN: You've indicated in your statement that there are no specific actions relating to those who were infected with blood and blood products within the elimination plan. Can you help us with why that is?

DR McCLEAN: So I think it is because the focus in this plan, which is very much the first phase of the elimination plan, was to focus on that larger group, and also to focus on this group, which are challenged to engage with services. So quite often it can be hard to reach this group to get them to go for testing and to get them to engage with treatment services. So I think

it was felt that particular effort was required around that group.

Having said that, another of the actions in the elimination plan was that hepatitis C was made a notifiable disease in Northern Ireland and that happened in summer of last year. So that's a relatively new thing. The important thing from a public health point of view about that is that every time someone is now diagnosed with hepatitis C, it's mandatory that the laboratory tells us in public health, and that then allows us to work with the clinicians involved and to work with people looking after the patients and the patients themselves to identify their risk factors, do contract tracing and really find out more about where they have acquired their hepatitis C.

Now, my understanding is that since the elimination plan has been published, the information that we have received is that we have not had a new diagnosis of hepatitis C associated with historic use of blood transfusion and blood products in Northern Ireland but the introduction of hepatitis C as a notifiable disease does allow us to systematically start to gather information about that in a way which we couldn't in the past.

MS FRASER BUTLIN: So in terms of making hepatitis C

a notifiable disease, you've indicated it allows the tracking of how many people are being diagnosed --

DR McCLEAN: Yeah.

MS FRASER BUTLIN: -- whose risk factor relates to blood and blood products.

DR McCLEAN: That's correct, yes.

MS FRASER BUTLIN: Dr McClean, would it also allow for any tracing backwards if someone has also been a blood donor?

DR McCLEAN: So I think that would be something that the clinical team and the Northern Ireland Blood Transfusion Service would be better able to answer. I can find more information about that and provide you with further detail on that but, if someone has been a blood donor, that will be a question for those services to investigate, but I can provide more information.

MS FRASER BUTLIN: I think what I was asking you, Dr McClean, is whether you were aware of any linking up between the notification of the disease and the Transfusion Service?

DR McCLEAN: So at the minute I'm not.

MS FRASER BUTLIN: The notifiable disease point is one aspect of the actions that have been taken in relation to what you've termed the "priority population". Are there any other actions that have been taken relating to

the priority population that you think would still impact on identifying and engaging with those infected through blood and blood products?

DR McCLEAN: So we have, and for number of years have, highlighted -- or run -- run information things around hepatitis awareness. So, for example, on World Hepatitis Day, the Public Health Agency would disseminate particularly social media posts and videos and information, and they will remind people or inform people about the risk factors for hepatitis B and C more generally. And one of those risk factors that the media content includes is highlighting people who have received blood products and blood transfusions in the time primarily before 1981 *(sic)* and '86.

MS FRASER BUTLIN: Could I turn you then to WITN7311004, please.

Sorry, Dr McClean, I've just seen on the transcript that you referred to blood transfusions primarily being "before 1981", did you mean 1991?

DR McCLEAN: Yes, before 1991, apologies.

MS FRASER BUTLIN: I'm not sure if it was a transmission issue or an error but we just want to make sure that the transcript is correct.

WITN7311004, thank you, Lawrence.

This the Northern Irish Regional Hepatitis B & C

Managed Clinical Network Annual Report 2020. Before we look at the content of it, could you tell us first of all what the network is, and what its purpose is?

DR McCLEAN: So the network is a collaboration of clinicians and -- from across Northern Ireland, those working in the regional hepatology centre who will be responsible for treating all our patients with hepatitis B and C, along with people in local trusts, and people who work in other areas, for example prisons, drug services, things like that. So it's bringing everyone together, along with service commissioners and the Public Health Agency to try to put in place the best possible treatments for patients with hepatitis B and C.

MS FRASER BUTLIN: If we turn to page 10, there is a table setting out the route of hepatitis C transmission recorded by patients presenting for treatment in Northern Ireland 2000 to 2020.

DR McCLEAN: Yes.

MS FRASER BUTLIN: We can see that, in relation to blood and blood products, the number is 128, out of a total of 1,696. So a percentage of about 7.55 per cent.

Would it be fair, then, that from this table it seems that there are still a reasonable number of people being identified as infected with hepatitis C from blood and blood products?

DR McCLEAN: That table relates to people who were diagnosed over the past 20 years, so the bulk of the people who are in that group for the blood and blood products group I imagine will have been diagnosed at the earlier part of the time frame, so in the early 2000s rather than in more recent years, and I think that number, whenever you look at it compared to the numbers in the statistical report, makes me think that we have identified certainly a large proportion of people in Northern Ireland who were identified -- or who were infected through blood and blood products.

MS FRASER BUTLIN: Then if we turn the page, we see the heading "Hepatitis C patient re-engagement", and I'm just going to read it out for those listening, and then ask you about it, Dr McClean.

"The Liver clinic has an extensive database of patients known to have HCV infection and in February 2019 it started using the database to try to reconnect with those with whom we had lost contact. A 'call back' process was started to trace and treat patients who were previously diagnosed as having a chronic active infection and referred, but who never attended clinic. Several of these patients were identified, contacted and offered testing to confirm whether they still had an active infection and then invited to clinic to be

assessed for the newer more effective treatments.

"Of those identified and contactable, only 7% came forward for specialist assessment and treatment and have since cleared the virus. The rest of those individuals identified were either uncontactable, refusing to engage, no longer living in Northern Ireland or had died.

"All those who were uncontactable or who did not attend appointments during the 'CALL BACK' process will be sent follow up letters and the outcomes of this will be reported on at a later stage during 2020."

In terms of the database of patients who were being reconnected with, would this include those who had contracted hepatitis C through blood and blood products, and had a previous positive test but who'd then not engaged with treatment, or not felt able to carry on?

DR McCLEAN: So the database is held by the clinical service, so it's held in the Belfast trust by the hepatology unit, so it will be anyone who they have engaged with in the past who have had a positive treatment and they've had contact with, irrespective of how they contracted their hepatitis C.

MS FRASER BUTLIN: In terms of the -- apologies.

In terms of the specific group of people who have been infected with blood and blood products who

potentially have not yet been identified, you said in your statement that you anticipate that actions will be set in relation to that group in phase 2 of the plan. Do you have any understanding of what those actions are likely to be?

DR McCLEAN: So I think that we are open to constantly reviewing our plan and our actions, and I've listened with interest and read the statements, particularly from England, around the efforts that they have made to further reach out to this group of patients, and I think it would be very helpful for us to take the learning from the various projects under way in England to see is there a way that we can refine testing, refine targeting of patients, to try to identify any remaining patients who may be undiagnosed in the population.

MS FRASER BUTLIN: I want to then move to some more general questions to all of you as a panel. First of all, if I can start with thinking about the English case finding search tool and the Bristol study. In terms of, Dr McClean, Professor Dillon, Dr Healy, what are your perspectives on whether a similar exercise would be helpful in Scotland, Wales or Northern Ireland?

DR HEALY: I think our intention is to wait and see what happens from the England perspective and the report on it. Separate to that, we are working on some

epidemiology work to try to better identify what the prevalence is within Wales, and an epidemiology colleague is looking at carrying out -- I forget the term, actually, but it's looking at all different risk groups, essentially, and trying to get testing carried out in various risk groups, pooling that together, multiplying it up to get an overall idea of prevalence which would capture some of what you're tying to ascertain. And I think that project hasn't been definitely funded but we're working on that and, if that's funded, we'd put that together with what they gather in England and then devise a strategy on the back of that.

PROF DILLON: From a Scottish perspective, we'll see what our English counterparts come up with. We have an ongoing project, again working with Professor Hickman's group in Bristol, looking at the epidemiology and the changing epidemiology of hep C infection in Scotland, and that is due to report in another two years' time. So we'll have more data from that in terms of the ongoing risk of transmission and whether that's falling.

The early cuts to that data suggest that the rate is falling and there are not hidden pools of transmission and some things are coming to an end, and we're not

seeing, with our record linkage, a huge surge of patients presenting late with liver disease, related to hepatitis C that was transfusion related.

MS FRASER BUTLIN: Dr McClean, do you want to add anything from a Northern Irish perspective?

DR McCLEAN: Just to say we'll also wait and see what the English work shows us and if there's any learning for us.

MS FRASER BUTLIN: All four of you have mentioned the impact of Covid on the ability to address and progress the elimination strategies. Post Covid, do you have any concerns about whether hepatitis C will be given priority in terms of resources and focus?

PROF FOSTER: I'll start with the English perspective. With no suggestion that the pace within the elimination programme will falter, we're looking ahead to the next year at similar levels of funding, the procurement contract with pharma finishes in 12 months time and we're already starting discussions about extending into a slightly different model.

So certainly in England there's no suggestion that we're taking our foot off the gas. A lot of it will be driven by the data that comes forward, how much left to do, but there's very much a commitment from a very high level to finish the job we started.

PROF DILLON: I think the decision is yet to be made in Scotland. We got stopped as we were starting, the teams were largely broken up and redistributed to Covid. Very few of us were still doing any hepatitis C work during that time. The epidemiological data is due to appear, as I said, later this month and the civil servants that are part of the committees that will be reviewing that will be reporting to ministers.

It would need a new pharma contract, it would need ongoing commitment to very a substantial increase, you know, having lost two and a half years of progress, it's now looking at delivering 6,000 or 7,000 patients into treatment a year, as opposed to 3,000 patients a year to achieve elimination, which is a very tall order. So I suspect that a delay to the elimination date might be the most likely outcome, but we'll see what's happened to the epidemiological data over the years of Covid. Whether there has been ongoing transmission or whether transmission has fallen during the lockdown is one of the unknowns at the moment. We're looking forward to seeing that date.

MS FRASER BUTLIN: You obviously have concerns about whether you'd reach your elimination target but, in terms of funding and staffing, is there any concern about returning to pre-Covid levels of your teams?

PROF DILLON: I think there is concern about that, where lots of people have been redeployed and haven't come back. The teams in Scotland weren't people who are focused solely on hepatitis C. They continued a number of other functions through needle exchanges, community pharmacies, et cetera. The way addiction services have been organised has changed dramatically during Covid and, whether they will return to the pathways that we had before, I think that's unlikely.

They will be different and so we'll need to start building those relationships all over again to encourage people who are involved with the populations who are injecting or have injected drugs in the past, and getting them back in sync with the hepatitis C elimination programme will be a new challenge to go forward with.

MS FRASER BUTLIN: Dr McClean?

DR McCLEAN: I think that our elimination plan being published when it was was a big challenge because it was right in the middle of Covid. It is only now that we're starting to bring our teams back and get key staff in post to be able to deliver this. So I do think that whilst it's been challenging at least we are now in a position where we're able to move forward and we have resources for key posts related to this.

MS FRASER BUTLIN: Dr Healy?

DR HEALY: On Tuesday I attended the first meeting of the elimination oversight group, which has a number of key individuals that -- key posts in Welsh Government and health boards. So there's definitely an appetite to move forward with elimination. However, at the same time, I'm very conscious that we're pitching for funding in a very resource-limited area and so I think -- I'm hopeful but I'm also realistic, and time will tell a little bit, in terms of where we get to.

MS FRASER BUTLIN: In terms of those sort of structural and co-ordination elements you've talked about, the issue of engaging with primary care colleagues has been raised by all of you. Why do you think it's difficult to engage with primary care colleagues? What are the challenges that you're facing?

(The witnesses laughed)

PROF DILLON: The GP workforce has fallen in terms of doctors, the demand has gone up, and it's another straw on the camel's back and I expect them to deliver more from a diminishing resources struggle. So that's part of -- and I don't see an imminent solution to that, in terms of recruitment into general practice, training new general practitioners, et cetera.

It's an aging workforce, large numbers of them have

retired in the last year or are on the verge of retiring and that makes it an increasingly difficult group to deal with. I think they've equally had, you know -- Covid has been difficult for everybody. But I think the general practitioners probably had a disproportionate impact on the workload and less resilience, and that has added to the problems and I think the general appetite amongst them for taking on something new and different is pretty low at the moment.

MS FRASER BUTLIN: Do others have any thoughts that they want to add to that?

PROF FOSTER: I strongly agree with John. It's an increasing demand on a fragile, limited and reducing workforce. So it would be difficult with -- public expectations of primary care seem to have risen dramatically and -- at the same time when the capacity to deliver those has been reduced. So it will be a significant challenge.

MS FRASER BUTLIN: The English idea of GP Champions was raised. Do any of you have any views of what could be done to improve engagement with primary care colleagues?

PROF DILLON: To be honest, we've probably moved away from using general practice as the major delivery workforce for this and we'll be looking to third sector partners and nurse-led and peer-led initiatives to deliver the

majority of treatment, and decentralising prescription away from medics into other partners in healthcare is the direction of travel in Scotland. And so I -- we don't anticipate general practice playing a -- having to play a large role in delivering elimination in Scotland.

DR HEALY: Yeah, I agree with that. We've decentralised, we're using different models of care to try to engage. I suppose central to the question you're asking is: how do we engage primary care in trying to ensure that there are no missed individuals from -- who may have received blood products in the past? They definitely need help in that regard and, hopefully, the program of work that they're doing in England in terms of identifying at-risk people will help.

How we then encourage those individuals to get tested is a challenge, isn't it, I think. Yeah.

MS FRASER BUTLIN: Dr McClean do you have anything you want to add to that?

DR McCLEAN: I concur, that for general practice it's such a huge workload.

MS FRASER BUTLIN: Professor Dillon, you've indicated you're sort of moving away from using GPs too much but, in terms of that awareness and education element, so that if a patient presents saying, "I think I've been infected" or with a raised ALT and testing is needed,

what could be done to assist GPs to be more aware of hepatitis C and the need to test?

PROF DILLON: So I think from the -- from presenting with symptoms of tiredness, fatigue and abnormal liver function tests, decision support tools such as intelligent Liver Function Testing, which is now part of the clinical diagnostic centres' policy in England and is also policy in Scotland, will help, because then the testing becomes automated so that they -- it doesn't require a specific thought about hepatitis C, it's part of -- the whole panel is tested on those abnormal test patients. And using the appropriate normal ranges for ALT will find those patients that had previously been missed by using ALT strategies before which were at a normal range that was too high. And so we will find those patients. But, as we've seen from the statistical estimates of how many people there are, we are dealing with a small number of patients, unless those statistical estimates are wildly inaccurate, which, with the thoroughness they've been done, seems unlikely.

MS FRASER BUTLIN: Do any of the rest of the panel want to add anything?

PROF FOSTER: No.

MS FRASER BUTLIN: No. In terms of other steps that might be taken to identify individuals, do you think a public

awareness campaign should be commissioned about the risks of hepatitis C from blood and blood products?

PROF FOSTER: From the English perspective we've looked at this very carefully, considered it, and at this stage we don't think we have enough information to guide us there. I think at some point a public information campaign for hepatitis C and blood-borne viruses might be very useful but I'm not sure where I would target that at the moment. Are we targeting people who used drugs 20, 30 years ago? Are we targeting immigrant communities? Are we targeting people who gave birth in -- 20, 30 years ago? So I think until we have information about where we would want to target that, I wouldn't want to advocate it. Essentially, you get one shot at a public health campaign so you've really got to get the targeting right and I'm not sure we have. And I think we'd want to look at a public health campaign for blood and blood product recipients in a very targeted fashion.

It may be better to say, "If you have a 20-year old child, you need to be tested for hepatitis", and we might be able to do that by a more effective way than a public awareness campaign. So I'm not yet convinced but I think we would certainly be attuned to the idea if it was shown to be valuable.

DR HEALY: I'm not best placed to answer that question because that's not my expertise, but we have discussed it within Wales over the years, and people who know a lot more about this than I do have pointed out that people tend to remember the very successful public health campaigns but they don't remember the unsuccessful public health campaigns, and there is a degree of anxiety around launching an unsuccessful public health campaign with all -- which is costly, and money that might have been better spent elsewhere. So I'd agree with Professor Foster in terms of, if we are going to launch one, then we need to make sure we get it right, because you only get one chance.

PROF DILLON: In Scotland we did it a decade ago. It wasn't terribly successful, there was no appreciable increase in the number of patients diagnosed, it was focused across the whole spectrum of possible risk factors and encouraged people to access testing. There was a corresponding awareness-raising campaign amongst primary care colleagues, so they were ready to expect it, and we didn't notice an impact from it at all, despite spending I think upwards of £7.5 million on it.

MS FRASER BUTLIN: Dr McClean, you're nodding. Is there anything you want to add?

DR McCLEAN: I think it's really important that we remember

that public health information campaigns cost a lot of money and we need to make sure that they're targeted appropriately and that we know what we want to get out of them, so would echo what others have said.

MS FRASER BUTLIN: And what are your views of whether a wide-scale hepatitis C screening programme of the public should be undertaken, perhaps for those over a certain age or perhaps for women who have got -- or who have given birth at a particular time frame? What are your views of something like that?

PROF FOSTER: I think, again, almost refer to: let's see what the data shows. If the data shows that that would be helpful and if people over the age of 50 -- between 50 and 70 are coming up in all of our testing, then that would be a good thing do. But I tend, I'm afraid, to follow John's approach in Scotland, which is that we should be focusing on liver health, and hepatitis C is part of that.

Hepatitis C is a minority cause of abnormal liver function tests nowadays. If we go for abnormal liver function tests we may get better buy-in from primary care physicians. We'll certainly get a lot bigger hit, we'll find a lot of people with manageable disease, and in so doing will also pick up any remaining hepatitis C. So I would at the moment, with the data we have, be

advocating an abnormal LFT pathway rather than a hep C pathway, but we'd be very sensitive to data and will change if necessary.

PROF DILLON: I would agree with Professor Foster. It's always nice when he takes one of my ideas but in terms of the health economic arguments, if we were to set up a screening programme or a case-finding programme, it would be more cost effective to look at the broader health implications of liver disease in general rather than hepatitis C specifically and that would be an easier argument to win in terms of the allocation of resources, because it wouldn't cost much more to look across the whole spectrum of liver disease, rather than just focusing on viral hepatitis.

MS FRASER BUTLIN: And I think you think you'd get better buy-in from GPs?

PROF DILLON: Yes. Absolutely. It comes back to Professor Foster's earlier comment that, if you have people doing lots of tests and never finding it positive, people lose faith in any form of screening programme and so, if we were to broaden it across liver disease, you would find liver disease -- it's about 3 to 4 per cent have significant occult liver disease that requires some form of intervention and so, amongst that, it will be the hepatitis Cs and hepatitis Bs.

DR HEALY: Just one thing to add, whenever you are doing any screening programme, you have to consider the potential harms that might come from a screening programme. So I think people tend to think relatively simplistically in so much as "If we screen, we'll find people with infection and we'll treat them", but you have to take account of the fact that some false positive tests will occur and any screening programme around liver disease you'll get false positive tests around whatever test you employ.

So they do have to be carefully considered. It's not quite as simple as it at first sounds.

MS FRASER BUTLIN: Does anyone want to add anything else to the discussion?

DR McCLEAN: I think I would add that, for any population screening campaign, we'd want it carefully considered by the National Screening Committee. We have a range of population screening programmes in the UK, all of which are considered carefully by that committee because, as others have said, there are harms, and as well as that, if we headed out and identified lots of people with -- who might have a condition, we then have to have of the services in place to actually assess and diagnosis them. So it's really important that any decisions are taken through of the National Screening Committee on this.

MS FRASER BUTLIN: As a different thought in terms of identifying people, in Wales there's obviously the pharmacy testing but only in relation to needle exchange. What are your views of whether extensive provision of hepatitis C testing should be available at that community level for anybody attending a community pharmacy?

PROF FOSTER: In England we found it very difficult to engage with pharmacies and we're very envious of the success that our Scottish colleagues have had, and a lot of that is related to the workload in pharmacies, they're busy. The yield in terms of hepatitis C test positives has been relatively low, so they haven't been terribly well reimbursed. There is a fear, I think, perhaps an overblown fear, that if we were to say to pharmacists "We'll pay you £15 for testing anyone who might have hepatitis C", a smart community pharmacist would put a very junior individual at the door and test thousands of people a day to very little gain.

So I think we would want to look very carefully at what the added value would be of community testing in pharmacy. We do want more testing but it does need to be appropriate testing, and I think it's striking that balance between spending a lot of money testing a lot of people. And I think the comments from Dr Healy were

entirely apposite, that testing everyone does yield false positives and they become very distressing to all involved.

We're just dealing with -- we've done a 10,000 patient survey in addiction services. I have two false positive HIV tests and those people are very distressed by that. So there is a cost to a test and no matter how good the test, when you test a large number of people you will find some, and that will cause harm.

MS FRASER BUTLIN: Any other views?

PROF DILLON: In Scotland -- in Tayside, my part of Scotland, we've had good success using community pharmacies with testing focused on needle exchange and opiate substitution therapy recipients. We're in the process of negotiating a national pharmacy contract around doing that for the whole of Scotland. It's become part of a more generalised contract, which has been bogged down a little recently, and so those negotiations are ongoing.

MS FRASER BUTLIN: But what would your view be of extending that to perhaps a particular age group who would be able to walk into a community pharmacy and request testing?

PROF DILLON: I think for the general population, if they don't have a particular risk factor we would find more false positives than we'd find true positives, so

I think it would be a risk because I think the population prevalence outside those with an overt risk is very low. Now, someone who is particularly concerned and who is going in to ask for a test, they probably think they have a risk factor and therefore the pick-up rate would be justified for that. So I think it would be that assessment of the risk factor before randomly -- because of the stigma associated with hepatitis C and a more anonymous testing route for those people who aren't still engaged in opiate therapy or injecting behaviours, then that facility might be a more neutral ground. Although the online options that Professor Foster has described earlier on might be a good option for that.

DR HEALY: Similarly, very keen to see barriers to testing lowered in appropriate populations. As colleagues have alluded to, you protect against the harm of screening by making sure you're targeting an appropriate population with at least a decent prevalence to protect against the risk of false positives. So yes to reducing barriers, but we have to do it intelligently.

MS FRASER BUTLIN: So perhaps -- I think I'm hearing from Scotland and Wales, and perhaps also Northern Ireland can indicate the -- Dr McClean, your views -- of the postal and the online portal giving access to postal

testing might be more appropriate than wide-scale community pharmacy testing; would that be your views?

PROF DILLON: I think it overcomes the barriers of stigma, et cetera. It allows -- it makes it easier for people to make that choice that they wish to pursue a test, and I think that's a lot of attractions to it, rather than having to go and explain yourself to someone in a pharmacy as to why you want a test, which I think would be daunting for some people. So I think the online tests with, you know, supportive advice, from what I've seen of the portal, in terms of appropriate testing might be the better way forward.

MS FRASER BUTLIN: Dr McClean, do you any views on the online portal?

DR McCLEAN: I'd agree with that as long as it provides information and is targeted in some way, so that it doesn't become like a backdoor random kind of testing process.

DR HEALY: Yeah, it's the targeting, I think, which is key.

MS FRASER BUTLIN: Final issue. When considering how to avoid something like this happening again, in terms of the infected blood situation, and in terms of the challenges that have been faced in tracing people who have received blood and blood products, it might be suggested that record keeping is important and it might

be suggested that there are matters in that regard that need to be addressed.

Professor Dillon, you explain in your statement that compliance is suboptimal with the guidelines that recommend that transfusions are included in the discharge communications with GPs. Can I ask the panel broadly what your views are on that issue of communication from a hospital setting to a GP, and record keeping that indicates someone has received a transfusion?

PROF DILLON: So I think that has now moved away from the ancient clerk books of times gone by, and blood transfusion services now have extensive records of who has received which unit of blood from whom. And indeed all of the blood products, I think, in terms of if the -- if we were going -- if there is, you know, a new infection or a new complication from blood transfusion that we need to think about going forward, for the last decade, two decades, we now have very sophisticated records that would allow us to identify exactly who received what, and what their risk factors were. And so I think that's changed. And so we're not going to be going through GP records and old hospital records -- was always the second best option, which we've had to use because there wasn't a best option in terms of we didn't

have sophisticated records for blood transfusion, which we now do. I mean, the Health Service had less sophisticated records previously. They are now better and I think, in terms of blood transfusion, we'd be able to trace those patients very effectively.

MS FRASER BUTLIN: I've been asked to ask the panel whether any of you have any residual concerns about the current system of record keeping that would allow that tracing to take place? It may be that you can't assist us on this question because it's not really your area.

PROF FOSTER: I agree with John. I think the system is so much better. I'm not an expert on data transfer and data linkage but we do seem to have an awful lot of systems which talk very poorly to each other and we have a lot of systematic barriers to data transfer. Data protection in the Health Service is something we treat very carefully and perhaps too carefully, in that GP records often aren't available for treating doctors in hospitals and vice versa.

So I think there is certainly work to be done linking up the data systems and having a more grown-up conversation about what data can be shared with which healthcare professional, and I think those conversations are beginning. But I think the systems are much, much better but not perfect.

DR HEALY: I'm not aware of any risks but that question would be better directed towards the Welsh Blood Transfusion Service. I also agree with Professor Foster that the risk in the future may not be related to blood transfusion; it's a much broader topic around record keeping in general and records being available, and there's definitely a lot more work that needs to be done within the NHS in relation to that, as a whole.

MS FRASER BUTLIN: Dr McClean, I don't know if you have any views you want to add?

DR McCLEAN: No, just to concur and say that, as we move towards electronic records that patients have access to as well, I think that will better inform patients about their own treatments as well.

MS FRASER BUTLIN: Sir, those are the questions I have for the panel. We obviously now need a break to allow recognised legal representatives to provide me with any further questions they would like me to ask the panel.

SIR BRIAN LANGSTAFF: Well, you've timed it very nicely to coincide with our usual break time for lunch.

MS FRASER BUTLIN: It was entirely intentional, sir.

SIR BRIAN LANGSTAFF: Very well, let's say not before 2.00.

I imagine the hour will give plenty of time for Ms Fraser Butlin to field any questions that Core Participants may have for you, which they will direct

through their own lawyers to Ms Fraser Butlin. But just in case there are more or, for that matter, late-coming-in questions, we'll say not before 2.00. You'll be told if it's any later. I can't tell you quite how long you'll be detained after that but it will be, I would hope, in plenty of time for your travel arrangements this evening.

MS FRASER BUTLIN: Thank you.

SIR BRIAN LANGSTAFF: 2.00, not before 2.00.

(1.03 pm)

(The Luncheon Adjournment)

(1.58 pm)

MS FRASER BUTLIN: Thank you. I just have a couple of questions I've been asked to ask you.

First of all, Professor Foster, in your evidence you said that you never had records from the interferon era. Can you help us at all with why that was?

PROF FOSTER: So the interferon treatment was administered locally by individual hospitals. There was no central registry of treatments administered. And we go back to the problem we have with notes that are missing, old handwritten notes going back to the 1990s. So unfortunately we don't have a central registry.

MS FRASER BUTLIN: A number of you described using the record of a blood transfusion within the relevant period

as a risk factor for hepatitis C, and 1991 being the end stop for that. I'm asked to ask that after the Inquiry report is published, will any findings that may be made relating to the end stop date be taken into account when publishing anything about the hepatitis C relevant period?

PROF FOSTER: I'm sure if there was a different conclusion reached we'd want to act on it and want to respond appropriately.

MS FRASER BUTLIN: And is that the situation across the nations?

PROF DILLON: Absolutely.

DR McCLEAN: Yes.

MS FRASER BUTLIN: Again, Professor Foster, a question for you. Dealing with the use of blood samples that have been taken for other reasons being tested for hepatitis C, can you tell us what the position is in relation to consent for testing?

PROF FOSTER: We are currently working through that process with the local teams in Liverpool, who are doing it as a research project. There is an issue as to whether it will be anonymised or whether patients will be pre-consented, but nothing will take place outside the jurisdiction of an appropriately constituted ethical review board.

MS FRASER BUTLIN: Finally, you've all talked about the utility of online portals for patients to access testing. What arrangements are being made or would you anticipate being made to ensure that those with less access to the Internet can still access that information? Perhaps if we start with what is being considered and then others, if you have a view of what might be considered.

PROF FOSTER: We see the web portal as giving us insights into populations that we're missing, and we would hope, and anticipate, that there would be a fairly broad spectrum of people that will access it. I think the idea that the elderly don't use the Internet is very much a myth, but that will identify populations at risk who can then be selectively targeted. So if, for example, we find a cohort of over eighties have unexpected hepatitis C, then we would start to think about ways we could implement. So we'll use it as the learning. It's another plank in our evidence base to what else we need to do, rather than a final game point.

MS FRASER BUTLIN: Do any of you want to add to that?

PROF DILLON: I don't think -- there isn't a one-size-fits-all solution and so I think having lots of options so people can choose according to their abilities and preferences.

DR HEALY: Yes, a similar response. It would be additional to other mechanisms for being tested. And if we became aware of a particular group that needed testing in a particular way, we would be very open to developing whatever is required in that regard, as evidenced by how we're expanding testing in so many different ways.

MS FRASER BUTLIN: Dr McClean, is there anything you would like to add?

DR McCLEAN: Similarly, we would want to make it accessible for all populations.

MS FRASER BUTLIN: Sir, those are the questions I've been asked to ask. I don't think there is anything further. Is there anything you would like to raise?

SIR BRIAN LANGSTAFF: I have no additional questions of my own.

MS FRASER BUTLIN: Professor Foster, is there anything else you would like to add before we finish?

PROF FOSTER: No, I think we've covered things very clearly, thank you.

MS FRASER BUTLIN: Professor Dillon.

PROF DILLON: I have nothing to add.

MS FRASER BUTLIN: Professor Healy?

DR HEALY: The only thing I'd add is I think you asked me earlier about looking back and I was talking about in the recent past. I didn't allude to the earlier

look-back in 1995 but I took that as for granted, yeah.

MS FRASER BUTLIN: Thank you.

Dr McClean, is there anything else you would like to add?

DR McCLEAN: Nothing to add. Thank you.

SIR BRIAN LANGSTAFF: Can I, for my part, thank each of you. I know that this is, in some respects, an imposition upon busy practitioners, particularly after what you've said about the stresses on the system following Covid and the backlog that there may be after that. So it is particularly valuable to have you here and what you have told us, particularly given the approaches in England and Scotland, has been most informative and instructive, and very helpful. So thank you.

MS FRASER BUTLIN: Sir, we obviously just need a short break to allow the panel to go and our next witness to attend. I know that's a little bit awkward having just had the lunch break, but perhaps we can just have ten minutes.

SIR BRIAN LANGSTAFF: Yes, so not before 2.15.

MS FRASER BUTLIN: Thank you.

(2.03 pm)

(A short break)

(2.14 pm)

SIR BRIAN LANGSTAFF: Dr Mulholland, let me explain the arrangements. You're talking to an audience here which

consists of those who were infected and affected, participants and Core Participants. To the left you have lawyers who represent various different interests in the Inquiry. And at the back left there are those who may, from time to time, include representatives of the press.

But beyond this room there is a wider audience, both here, in Aldwych House, and watching on YouTube or live stream. I can't tell you quite how many it will be but it will be probably in three figures and may be substantially so.

Ms Fraser Butlin will be asking you the questions but, first, Mary has to invite you to affirm.

Mary.

DR MICHAEL NIAL CONNOR MULHOLLAND (affirmed)

Questioned by MS FRASER BUTLIN

MS FRASER BUTLIN: Dr Mulholland, you're a practising GP and also the honorary secretary of the Royal College of General Practitioners; is that right?

A. That's correct.

Q. Can you tell us, in layman's terms, what the royal college's role and remit is?

A. The Royal College of GPs -- is to foster and maintain the highest standards of general practice and encourage that as we move forwards with new generations of GPs.

Q. As honorary secretary, what are your responsibilities?

A. My responsibilities are mostly around governance of the college and governance to the Trustee Board, and within that I have roles in supporting the membership team. I look at the clinical -- I oversee the clinical policy on behalf of the officer team as well.

Q. I want to address my next set of questions about the training of GPs, just so we can understand how GPs are trained and what role the college has. So, in terms of initial training to become a GP, what role does the college have within that?

A. So all doctors that want to become a GP enter GP training schemes, and the role of the college within that is to -- we set the curriculum for general practice training. We obviously oversee the exam at the end of general practice training. And to become a GP they then go through three areas of GP training that's overseen by the statutory education bodies around the four nations of the UK, but we bookend that training process with curriculum and assessment.

Q. In terms of those exams at the end, by passing those exams, then a GP is effectively allowed to practice in the UK as a GP?

A. Yeah, passing the MRCGP exam, the Member of the Royal College of GPs exam, is also used as a marker to get

your Certificate of Completion of Training, and that then is looked at by the GMC as the marker that you can then practice as a GP specialist in the UK.

Q. In terms of training on communication skills, can you explain for us what's required by the royal college before someone is signed off, licensed as a GP?

A. So communication skills come into the whole of the exam, and the tri-pass. We have a three-part exam, which includes clinical skills assessment, communication skills assessment. We've got workplace-based assessments and a knowledge test as well. Within each part of that, our curriculum has parts that will be tested in each stage. The most obvious one, looking at it, is the clinical skills testing, where communication is observed either in the workplace by the GP trainer or by assessors during the examination, and that's a core part that a trainee must part -- pass both the WPBA, the workplace -- and the communication skills.

Q. Just broadly, when you're assessing communication skills, what must a trainee demonstrate before they are passed? What is the college requiring of trainees?

A. So our communication skills, in the assessment, has been looking at particularly that they must have a knowledge, they must know what they're doing, and pay the right clinical management of a patient. They look at the

interpersonal skills. And the third one escaped my mind but it's generally to look at how well they communicate their ideas to the patient and understand where the patient's ideas are as well and take them into consideration as they have a whole assessment of their care.

Q. I think you also talk about the attitudes, feelings and biases?

A. Yes.

Q. Is that part of it?

A. Yes, that's part of it, and that we test it not only in those clinical skills, videos or simulated situations they're in, but also during case-based discussion work they do during workplace-based assessment. A trainer is then able to explore a case that they have gone through and then ask them specifically about how they have managed those cases and what their attitudes were during it and make an assessment based on that.

Q. In terms of Wales, Scotland and Northern Ireland, what's the position in those three nations? Is there a difference?

A. There isn't a difference in terms of the assessments. It's a four-nation exam that we run.

Q. You described the royal college bookending the initial training, but the training itself being done -- I don't

think you used the word when you were giving your oral evidence but in your statement you used the word "deaneries" doing the actual training?
A. Yes.
Q. First of all, can you explain what a deanery is?
A. A deanery -- within the UK there are four statutory education bodies, one for each nation, in England it's Health Education England. They then divide into regional bases of deaneries and they're -- I think there's 14 of them in the UK, across it, and the deanery then looks after a proportion of trainees that are closely related to the practices in that area.
Q. How much interaction then is there between the royal college and the local deaneries as to what should or shouldn't be included in the training that's given?
A. So the curriculum is there that the deaneries are training to. What we then get involved in is not actually what's being trained in, but how the assessments are quality assured. So we don't get involved in that training part. That is left to the education bodies for themselves.
Q. Then, once somebody has qualified as a GP, what role does the college have in relation to continuing professional development?
A. So, as a college, we, in common with the other medical

royal colleges, we provide education materials that GPs may turn to, or our members can turn to. Sometimes we provide materials for everybody, that can access freely, other times it's specifically for our members. But we do not say what anyone should be learning in that year because it relates very much to where a GP is practising where their knowledge gaps are, what they need to know more of, and that will be determined between the GP -- often at their appraisal they will discuss it with their appraiser, what they might be doing next. So we provide the resource but we don't have any say over what people do and who uses it.
Q. In terms of the resources you're providing, what sort of material is provided? What sort of topics does the college provide material on?
A. As a generalist college we provide material on almost everything that can be covered across medicine or the wide spread of it, and we provide it in different formats. Sometimes we do webinars, and they have become very popular during the pandemic, as we all turned to electronic means of communicating, but we do have face-to-face courses. We also have what we call our Essential Knowledge Updates, which are providing up-to-date knowledge on a quarterly basis that people can work through courses. And then there's a range of

CPD presentations and courses that you can go on online from it.
Q. How are new CPD resources provided or new topics chosen? What's the process that is followed?
A. So the college has a CPD strategy group that sits underneath the vice chair of professional development and standards, and they work through where they're hearing both the needs of new things that came up -- so obviously when Covid came up there was an immediate need that we needed to swap all of our CPD resource to Covid for several years. But also we then have experts or specialists or experts around the country that will feed in: "These are the new things that are happening in women's health", or infectious disease or whatever that comes up that's topical and new that we will -- they will try to put in. And so the strategy group put that in through the courses and through the conferences.
Q. The Inquiry has heard evidence from a number of female witnesses related to their hepatitis C being undiagnosed by GPs for a period of time, and their symptoms being put down to motherhood or perimenopause or menopause and then old age. Does the college's CPD material deal with anything around inequalities and discrimination?
A. Yes. I think in everything that we've done we've looked at where equality sits, and -- whether it's in the

curriculum, where we teach all the way through the importance of looking at biases that can come into thinking and in decision making, not just about the clinical diagnosis but about the people that are in front of you, whether you have unconscious bias there, but also, then, in our materials, the teams are conscious of what they're doing and how they fit them to make sure it is not discriminatory, that it does include everybody, and that any biases that might be present are addressed during the CPD learning.
Q. I'm asked to ask whether any of your materials cover listening to female voices, particularly in relation to their symptoms and when they're experiencing pain and how a woman's experience of illness is understood?
A. I don't know specifically on that, I'm sorry.
Q. Do you have any materials in relation to race discrimination as well?
A. Yes, there are.
Q. Can you tell us a little bit more about what work the college has done in relation to that?
A. So it's become a significant part of our college's work on how we address race discrimination. Over the past few years the college has been working on both the college diversity and inclusion of our membership, as well as our patient groups, as well. So there's been

a task group led by our Chair and COO who have led this through the college. There are materials being put out our CPD, I know, has got a new module recently on unconscious bias, our curriculum is being reviewed completely to make sure there are no biases within that and it has gone on in every area of the college that we have.

Q. We've obviously discussed the provision of materials by the college, but there are also commercial organisations who may also provide CPD materials --

A. Yeah.

Q. -- is that right?

A. That's correct, yeah. And many GPs will go to commercial organisations as well. We have 54,000 members as a college, there are many more GPs than that, and some people will exclusively use commercial providers as their CPD resource.

Q. Does the college have any involvement or oversight of those CPD resources that are provided commercially?

A. No.

Q. How is the continuing professional development of GPs monitored? You spoke a moment ago about appraisal. What's the system involved there?

A. So, annually, each GP has an appraisal with an external appraiser who has been appointed in England by

NHS England, who reviews with you your practice. It's usually a several-hour discussion. Before the pandemic, it relied on you providing an awful lot of evidence to show what you had done. That is less so during the pandemic, they have changed the model during that time, but your appraiser is there to check the areas of your working, that you're actually doing CPD that you're covering the areas of concern. If you've had any complaints or health issues or anything else those would be discussed during your appraisal as well.

Q. So, in terms of identifying a need for CPD that there is an area that perhaps the GP needs some input on or some training on, how is that identified?

A. Often we identify through self-reflection and the way they work. You obviously recognise that you have patients with problems that you've not been able to identify for yourself and that's all part of the GP training that we encourage people to be very mindful of what they do and don't know and reflect on each patient and the gaps in the knowledge there. But during your appraisal it's often a time -- we've also got, every five years, patient feedback and colleague feedback to arranged into that and, from that, you may find there are other issues that have come up, sometimes around not so much clinical issues but other skills that you may or

may not have and those would come into the appraisal and to your CPD at that point.

Q. Given that flexibility of GPs of essentially trying to work out what they themselves need to be trained on, is there a risk that some GPs may not receive the training that objectively they do require?

A. Yeah, I think that's fair. We never know all our unknowns and they come up, and what we try to train people to do is to understand that that's -- to make that a smaller and smaller part of their knowledge, that with the feedback that we get, and patient feedback very directly in practices, when you're working in teams you become aware of what others think your gaps may be and then you spend the time doing your work on that.

But yes, there is also a risk that as GPs we don't know everything and we try to cover as much as possible and are aware of the curriculum but there is a risk.

Q. In relation to communication skills, how is that addressed within the appraisal process?

A. That probably mostly comes in the -- from the multi-source feedback and the patient feedback that we get on a five-yearly cycle as part of revalidation. The patients are asked specific questions about your communication and how much they understood, how much you communicated, and how they felt about the consultation.

Did they get the information required? And that's probably where it's assessed most objectively on a five-yearly basis.

Q. That would then be discussed with the appraiser?

A. The appraiser then discusses that with you afterwards.

Q. If there was a concern that a GP perhaps had entrenched attitudes or an unwillingness to adapt familiar practices, rather than needing new knowledge, if I can put it that way, how does CPD address that sort of issue?

A. At that point, if the appraiser was picking that up they'd probably guide you in your professional development plan for the following year, to focus on that area. Because we have appraisers often in many areas for two or three years they would be often coming back to it the following year to check had it been done, what had been done, had you got new evidence? And sometimes appraisers will ask for new evidence that an area has been covered, if they felt there was a significant weakness in that.

Q. What resources or training programmes are available to somebody faced who is with an appraiser saying "Actually, there are issues here that need to be addressed" that aren't a knowledge question, it's an attitude question?

A. There are some courses available for that from commercial providers or from the college on other skills, whether it is bias training or that sort of thing. It can be -- there are courses there that doctors can access.

Q. Carrying on, on the same issue, if the appraiser has recommended something and the GP has not then engaged with that issue, what is the process then?

A. It's probably beyond my knowledge. I believe it goes towards the responsible officer for the area who then can address it.

Q. So it would be escalated?

A. Escalated.

Q. The Inquiry has heard about a number of guidelines that have been introduced over time and that there are a substantial number of guidelines coming in all the time. Starting off in England, how are GPs in England kept up to date with new guidelines?

A. With -- GPs face so many new guidelines coming often from specialist colleagues that it's very hard to keep up to date with that. There are many publications that will summarise guidelines and receive them in the post. The college tries very carefully in our CPD approach to inform GPs of new important things, our clinical policy team works on that as well as the CPD teams.

The organisations like NICE, the Institute of Clinical Health and Excellence, do send out emails regularly to tell us new guidelines are coming, so there's a wealth of places they come from. Choosing which ones you need to see is the harder part because there's so many, to know whether they relate to your primary care experience is difficult.

Q. How does it work in Scotland; are you able to assist with Scotland, Wales and Northern Ireland at all?

A. Probably no more than in my witness statement.

Q. Very well. For those listening, the witness statement reference is WITN7249001 and there is material there.

In relation to how best practice is embedded into GPs practice to ensure that day-to-day best practice is followed, how does that work for GPs?

A. Each practice will have their own systems and ways of doing that. As a college we encourage quality improvement activity and have seen that going into our QOF assessments, as well as for training, and so quality improvement activity also falls into our appraisals and each year quality improvement is something that GPs try to show that they've done. So that would be how we try and embed new things into practice to audit, review and improve the care.

Q. Moving out to being more specific in relation to

hepatitis C, what can you tell us about the work that the Royal College has undertaken to increase the awareness of GPs about hepatitis C?

A. Since 2006 or 7, I believe, the college has been actively producing guidelines and information for GPs to update them. From when hepatitis C was a newer disease and not known as much, the college took a leading role in developing that and has updated guidance ever since to try to keep GPs to the forefront. Hepatitis B and C we have modules on and learning CPD resources, and those have been provided and updated to -- 2021, I think, was the latest review we've done of them.

Q. If we could turn to the guidance that the college produced in relation to the "prevention, testing treatment and management of hepatitis C in primary care", WITN7294006 -- I'm sorry 7249006. Apologies, I've got my numbers wrapped the wrong way.

We can see it's the Royal College of General Practitioners' guidance and if we turn to page 3, we can see the contents page setting out broadly what the guidance covers, including information about what hepatitis C is, the natural history of it, making the diagnosis, testing in general practice, referral and then over the page, treatment.

If we can then carry on to page 11, please. We can

see the heading "Transmission of hepatitis C", and further down we have the subheading "Blood transfusions and blood products":

"Prior to the introduction of screening of all blood donations in 1991, there was a risk to recipients of blood. A heat treatment process to protect blood clotting factors (used in the treatment of haemophilia) against hepatitis C and other viruses was introduced in the mid-1980s (treated Factor IX available in 1985 and Factor VIII in 1987). There is a high prevalence of hepatitis C in people with haemophilia who received untreated clotting factors before these dates. However, [hepatitis C] should still be considered in patients from overseas or who have travelled abroad, who have had blood transfusions or surgery."

This paragraph might be read as having a particular focus on those with haemophilia and those receiving treatment abroad, with only a relatively brief mention of those who have received blood transfusions in the UK, prior to 1991. Could you help us with why that emphasis might be there?

A. I think this was the 2006/7 guidance and I wasn't part of it at that stage. Whether it was that was the extent of the knowledge, I know that in the more recent documents that we've published, in the learning modules

that there are, it focuses much more on blood transfusions as well.

SIR BRIAN LANGSTAFF: I note in passing that in the middle of the second-last sentence on the page it says:

"There is a high prevalence of hepatitis C in people with haemophilia who received untreated clotting factors before these dates."

In other words, before 1985 and 1987, so far as Factor IX and Factor VIII were concerned.

I wonder whether that is strictly accurate, Ms Fraser Butlin, because the evidence which the Inquiry has is certainly there was a product in England produced by BPL which was effective in respect of eliminating hepatitis C non-A, non-B, as it was called at the time, but that didn't mean that commercial products, which formed around about half, if not more, of the products supplied had the same protection, and it ought not to be thought, I think, ought it, Ms Fraser Butlin, in accordance with the evidence that we've heard, that commercial product was free of hepatitis for some time after that?

MS FRASER BUTLIN: Absolutely, sir. You've pre-empted a further question I was going to raise of why those dates had been used and --

SIR BRIAN LANGSTAFF: What does the footnote say?

MS FRASER BUTLIN: If I can just take a moment, footnote 41. It refers to The Lancet study of 1997 by Derby, Ewart, Giangrande and others in relation to the Haemophilia Centre Directors Organisation "Mortality from liver disease in haemophiliac men and boys in the UK".

SIR BRIAN LANGSTAFF: Yes.

MS FRASER BUTLIN: So it just takes you to a reference but it doesn't deal with that issue you have raised, sir, as to whether that is actually an appropriate date.

SIR BRIAN LANGSTAFF: Yes, thank you. Well, I don't know if that's been corrected in recent editions or is this the most recent edition?

A. No, that's 2007, which is the first information that the college had produced on hepatitis C at that stage. So I'm sure in more recent editions it's been corrected but I'll look to make sure --

SIR BRIAN LANGSTAFF: Well, you're sure?

A. I will make sure it is.

SIR BRIAN LANGSTAFF: You well make sure it is. Thank you.

MS FRASER BUTLIN: Just staying with that paragraph and that emphasis on transmission in relation to those with haemophilia and transmission where blood has been received abroad, do you think that that is the understanding of many GPs, that that's the primary issue of blood transfusion and blood products and transmission

of hepatitis C, rather than a significant awareness of those who have received blood transfusions in other circumstances, in terms of obstetric care or trauma or something like that?

A. I think today people are much more aware of a blood transfusion having been somewhere that patients received the blood and it was infected at the time. So I think the knowledge now would be greater than it was whenever that was 16 years ago, 15 years ago, that it's much more widespread in UK centres, and it's an issue for GPs to be aware of.

Q. But even as relatively recent as 2007, would it be fair that perhaps the emphasis wasn't on those who had received transfusions in the UK?

A. It would appear so from this.

Q. Could we then turn to page 15 of this document and we see the heading "Who should be tested", and it says this:

"The following people should be offered a [hepatitis C] antibody test. It is good practice to offer HIV, [hepatitis A] and [hepatitis B] testing along with [hepatitis C] after the appropriate discussion."

Then at number 4 we see:

"Recipients of blood (before 1991) or blood products (before 1986 in UK) and/or organ transplants (before

1992)."

So the same issue about the dates arise.

Then number 12:

"Consider any patient with abnormal liver function tests (LFT), especially elevated alanine aminotransferase (ALT)."

In terms of the recipients of blood or blood products, it might be suggested that this would assume someone knew they had received blood. Was there any recognition then, is there any recognition now, in relation to the problems with medical records showing someone's had blood and indeed the knowledge of a patient who might have been unconscious, whether they've had blood?

A. I think there's an awareness now that blood was given in a different way in the 1970s and '80s than it is now, without the very strict tracking of where blood has come from and who it has gone to and I think we'll be aware that in our older patients they may not have knowledge of having blood during surgery or other procedures at the time, nor would GPs have been aware that that necessarily was being transferred to us through records.

Q. In terms of the point 12, of considering any patient with abnormal liver function tests, when, as a GP, would you consider testing or is the Royal College guidance on

testing a patient when they have abnormal liver function tests?

A. Yeah, I think we would now look at the NICE Guidance, that's quite clear on when you should be testing and when you should look at an abnormal ALT and the tests that should be following it, one of which is hepatitis screening, but also ultrasounds and tests. The more common things that would produce this in patient groups include fatty livers and alcohol-related disease. So we would have those in that screen as well, as well as ultrasounds and hepatitis screening.

Q. Then if we turn on to page 28, please. We see the heading "Ongoing care", and we see a subheading -- if you just go down to the bottom of the page, please, Lawrence.

You see the heading "Ongoing care" and then a subheading "Ongoing care during treatment, usually in hospital", so there's a discussion there of blood tests, ongoing advice regarding injecting medication, ongoing support.

Then the next column, please, "Ongoing review/care after treatment", with the relevant PCR testing.

Then the next heading "In general practice", there are a series of points dealing with support of a patient during their treatment for hepatitis C, provision of

ongoing general medical services to support the patient through the treatment process, supporting patients on therapy, giving practical advice to them on managing side effects, ongoing support, ongoing harm reduction information, et cetera, and some points about referrals.

It appears from this guidance that the ongoing care in general practice in relation to hepatitis C comes to an end when someone achieves a sustained virological response. Is that fair, of what the guidance suggests, or is there guidelines about what happens to the patient after they've achieved sustained virological response?

A. I think treatment for hepatitis C has changed so much in that time that our awareness in the hepatology units, the secondary care colleagues, we would refer very quickly. The management of that disease tends to sit with our secondary care colleagues until they have reached an endpoint which, I think these days, would not just be on viral clearance. We would then get information back as to what follow-up was required in primary care or in secondary care, as well.

The main bit that stays with us and has always been there is the holistic, ongoing care of the patient, who has ongoing health needs. So that stays with general practice and often that involves the support in managing day-to-day living, as well as psychological and

everything else that we do as part of a GP service. But the disease itself would now be managed in secondary care.

Q. So you've indicated there's up-to-date guidance which, sir, I will ask those in the team to identify and ensure that they are available on Relativity as soon as we can. You've discussed some of the education materials that have been produced. Have there been any other measures taken to increase awareness of hepatitis C?

A. I think in each of the countries around the UK the RCGP has done different things. Within Scotland, where they have a high IV drug use population, where hepatitis C is more common, they have done specific Scotland-related initiatives. Beyond that, I'm afraid I don't know.

Q. Has there been anything else in England that you're aware of?

A. Not that I'm aware of.

SIR BRIAN LANGSTAFF: Could we just go back to the very first page of this document, because something caught my eye in passing which I may want to ask a question about.

MS FRASER BUTLIN: Of course. Sir, did you mean page 1?

SIR BRIAN LANGSTAFF: I do.

MS FRASER BUTLIN: Do you mean the page we looked at --

SIR BRIAN LANGSTAFF: The cover page, yes.

MS FRASER BUTLIN: The cover page.

SIR BRIAN LANGSTAFF: I don't have the question, I think, any more. Let me tell you what it arose out of. The prevention, the drug -- the document is prepared by the bodies set out there, and the first one caught my eye, which was the RCGP Substance Misuse Unit, and then the Sex, Drugs & HIV Task Group, which -- obviously someone has got to write it -- but it might suggest, particularly given your reference to unconscious biases, that someone -- not yourself, I suggest -- but someone reading this, might think "Oh, this is about this sort of area", whereas, at this time in 2006, it wouldn't have been really, would it?

A. It --

SIR BRIAN LANGSTAFF: It might have been more by way of intravenous drug use but certainly there will be quite a large component from those who have been infected by blood or blood products?

A. I think at that time -- I was talking to our president Professor Dame Clare Gerada yesterday about this paper that she was one of those that was involved in the Drug Misuse Unit at the time, but that was where the focus was. It was in the IV drug use population where hepatitis C had just become a real issue for them at that stage, and we were understanding that this was the first time that GPs were being given information around

that, so it did focus on this area.

I think, at that stage, the awareness of it being a blood transfusion as being a major contributor to hepatitis C wasn't there as much at the time, amongst the general practice side anyway.

SIR BRIAN LANGSTAFF: One of the side effects of that would be that when patients came in to see a GP, they might be faced with, "Well, what drugs have you had? What alcohol have you been taking?" That sort of approach, rather than asking questions about transfusion.

A. Absolutely.

MS FRASER BUTLIN: The next series of questions I want to ask you relates to what might be said in submissions to this Inquiry, that there remains a considerable knowledge gap for many GPs about hepatitis C, and there are a series of scenarios I want to discuss with you. One issue that's been raised is that sometimes someone might present to a GP over a period of time with non-specific symptoms and mildly deranged liver function tests, but hepatitis C testing doesn't follow for some time.

What could be done to improve the knowledge and awareness of GPs about the need for testing for hepatitis C? Or do you think that issue has now been addressed?

A. I think the awareness will be greater now, that people are aware that hepatitis C is a disease that's been transferred in blood transfusions as well as through intravenous drug use.

There are always -- a need to increase the knowledge of specific diseases, of which, as a college, we hear many, all the time, of things that where GPs have taken time -- time to recognise disease. But I think it's something, as a college, we're aware of, particularly me attending today, has focused our mind on where we sit in that blood -- in making GPs aware, again, of hepatitis C.

I know my Scottish colleagues have done more recently because with drug use in Scotland it has been more of a problem, that they've needed to inform their members because it was something they were all seeing all the time.

How we do that, I'm not sure at this moment, but certainly something we can consider as we move forward.

Q. Another scenario might be where someone has gone to their GP and asked for a test for hepatitis C. The Inquiry has heard evidence that, in some circumstances, some GPs have either said it was unnecessary or said that if the person had received an infected blood transfusion then they would have been identified in the

look-back exercises that had already taken place.

The Inquiry has also heard evidence about the limitations of those look-back exercises. What could be done there, again, to improve the knowledge and awareness of GPs about the issues surrounding infected blood and the limitations of previous look-back exercises?

A. I think doctors in general now are much more aware of the risks of infected blood, not just for patients, but, as we've run through hospitals during this time, of needlestick injuries, everyone is very aware that the screening for that includes hepatitis as well as HIV and other diseases. So I think we're aware of blood-borne disease as a real concept when maybe 15, 20 years ago it wasn't in people's minds as much.

The look-back exercises, general practice records are very good but only very good with the information that general practice receives. And so if -- blood transfusion will not be given in primary care except for very specific military circumstances, I'm told, but -- so what we rely on is the information coming to us and coding it. One suggestion I was given this week is that on the electronic platforms that we do our consultations on could have, as part of the onboarding for a new patient and the new patient screens, not just what your

weight and alcohol is but have you ever had a blood transfusion? So some of those might improve that.

Q. I want to come back to that thought in a moment. My question was slightly different, in that how could -- what could be done to improve the knowledge and awareness that look-backs weren't perfect in the past, there were limitations, and so perhaps to address the issue of where a GP might say to somebody, "Don't worry, if you received an infected blood transfusion you'd know about it"? What could be done to address that scenario?

A. I think that's probably an issue beyond general practice, that is information to the public at large, not just doctors, that look-back wasn't as effective as we might have perceived it to be. And being aware of those limitations to it, that's something that could come to doctors, to be aware that your look-back exercises weren't quite right or could come to the public the other way round. So we're all aware of it together. But I think that's not knowledge GPs would necessarily have without somebody informing us that the look-back hadn't been as accurate.

Q. Thirdly, in terms of evidence of people who have had treatment for hepatitis C, they've achieved a sustained virological response but they continue to suffer ill health, the Inquiry has heard some evidence where

GPs have then dismissed those concerns because they've reached a sustained virological response. Again, what could be done to improve the knowledge and awareness of GPs about the ongoing health issues that arise from chronic hepatitis C, even after having sustained the virological response?

A. I think some of those are dealt with in the newer CPD modules that I've looked at recently. I think that awareness of hepatitis C as being a disease that is there with long-term sequelae to it is something that we could work out through the CPD side.

I was just thinking about the first question you asked me about the person coming with non-specific symptoms, and there are so many non-specific symptoms that present to general practice every day that the diagnostic process is based on step-by-step working through them, and it is that awareness that when we get the abnormal result, it is time to do the next step. And hopefully in our more modern publications we do have that, that raised ALT goes ahead to the hepatitis screen.

Q. There's obviously a wide range of resources that the Royal College is providing in terms of CPD. It might be submitted, in light of the ongoing difficulties -- the evidence of ongoing difficulties in terms of GPs having

that awareness, it might be suggested that this is a cultural issue rather than a question of more education. What can be done to change the culture of how GPs operate?

A. Can you be more specific on the "cultural" issue?

Q. That although resources are being provided, change isn't necessarily happening on the ground. I think it is a general question of, how does one translate CPD and knowledge into change on the ground?

A. I think, because of the nature of general practice, each GP will probably have a different set of learning needs each year. What we can -- to mandate that every GP in the country would do hepatitis C training each year, or even once in the next five years, may mean that many GPs that don't see hepatitis C as part of their workload, because their patient population is different, don't do the training, and the others that really need it maybe miss out for three or four years. So we tend not to mandate anything specific except resuscitation training and safeguarding training as the two things that we do every year or every few years as part of a requirement. But everything else is, hopefully through the appraisal process and the GP's reflective behaviour, picked up and done that way.

Q. But in terms of those who may have been infected through

a blood transfusion, would it be fair, then, that because in their region there weren't so many people who were infected with hepatitis C through other means, intravenous drug use, their GP might not perceive there to be a need for that training?

A. I think with the current awareness, and I suspect from the college as we put it out again, that I've been here and will be informing members of that, that hepatitis C will rise up and the importance of checking through or reviewing patients that have had a transfusion in the past when you've got it on the records, or with patients if they tell you about it, that hepatitis C is one of the risks and will have been coming through that and we should be checking them.

Q. From your perspective, how effective are financial incentives such as quality and outcomes, framework payments, at changing approaches in general practice?

A. I think that's probably one for our policy team rather than for myself. The QOF payments are -- they're -- I don't think there's any good evidence on how effective they are for any GP to achieve change. People strive to provide quality, and in fact when we had quality improvement modules as part of the QOF, the college supported them as a way to move them forward but, actually, looking at specific areas rather than just

getting points for numbers.

Q. Could you see a case for incorporating hepatitis C testing or hepatitis C-related outcomes into a framework such as the QOF framework?

A. I think that's probably beyond the college's remit.

Q. Can you see a justification for assessing or spot checking GPs for having undertaken hepatitis C CPD?

A. No, I think is probably the answer. I think if we were specifically focusing on one disease, it will mean that the GP's doing something different and may miss other real learning gaps they have for that time. And it's hard to know where that process would stop. Would we spot check on every disease and see had we covered it? We'd hope through the appraisal process, again, that that would be picked up if there were gaps that were significant.

Q. Finally, in terms of -- obviously today we've been talking a lot about identifying individuals who have been infected with hepatitis C by infected blood and blood products but who haven't yet been identified. Practically, what would the issues be, both positive and negative, of having a mandatory requirement that patients over a certain age are asked if they have had or suspect they may have had a blood transfusion in the past to then enable them to be tested?

A. I think the biggest issue that springs to mind is resource, and how that would fit in to what's an overstretched, under-resourced -- the workload that would come with that, I think that would require an additional service as well as -- in addition to general practice, to actually have the resource to be able to do all these tests and follow up appropriately. Because inevitably I would feel we'd pick up patients who have positive hepatitis C that didn't know about it who would need the time and the expertise of someone to go through that with them rather than just being told, "You have a result that we've picked up in a test." It's not the same as -- the screening programmes that do go on have all been approved by the National Screening Committee, and they have the resources behind it to support the patients that have positive diagnoses. And I think if it was just as a mandatory requirement for general practice there would be no guarantee of that support and the systems were -- there alongside it, if we had -- if it came along.

MS FRASER BUTLIN: Those are the questions I have for Dr Mulholland. I obviously just need a short break to ascertain whether there are any further questions from the Recognised Legal Representatives.

SIR BRIAN LANGSTAFF: How long do you think you might need?

MS FRASER BUTLIN: I think probably just ten minutes or call it 15.

SIR BRIAN LANGSTAFF: Well, we're getting close to the first afternoon break, so let's roll the two together, shall we?

MS FRASER BUTLIN: Yes, of course.

SIR BRIAN LANGSTAFF: -- and allow people to have a cup of tea, if they want.

Let me explain, Dr Mulholland. Those who are Core Participants and are represented have a right, through those legal representatives, to have questions put to you by counsel after hearing your evidence. Plainly, they haven't heard it all -- or haven't had a chance to reflect upon everything you've said just yet. They will, in the next 20 minutes or so. I can't say how many there will be. There may be a number of questions, there may be very few, but we will say not before 3.20 we'll come back. If it's any later than that, it'll because there's a late question coming in, and you'll be told. But otherwise, not before 3.20.

(3.01 pm)

(A short break)

(3.19 pm)

SIR BRIAN LANGSTAFF: Yes?

MS FRASER BUTLIN: Dr Mulholland, I've just got three

questions, and they address various different things from our earlier discussion.

This morning, with the panel who gave evidence, it was discussed whether there should be requirement on GPs to test people for hepatitis C on a 'while you're there' basis, so much like blood pressure and diabetes.

A. Mm-hm.

Q. What would be the issues in terms of funding and staffing that would arise were such a requirement imposed?

A. I think the staffing is the biggest challenge. GPs run as independent businesses. We have a staff ratio that allows us to do the work that we know that we have. Anything we add in in addition to that means that the same people are doing an additional job rather than anything else, so probably reducing the work they're doing in some other area. So I think who would do this work if there's an additional -- if there's additional blood tests. Because it won't be while you're there, it would be at another appointment that you get your blood taken, usually by the phlebotomy team. So it really is around the workforce and how that would be fitted into whatever is the overstretched workflow problem we have in general practice already.

Q. Do you think it would be valuable for GPs to have

specific training on the issue of infected blood?

A. That's a difficult question because every disease it would be good for us all to have specific training on, and, as part of the professional process of CPD, it's self-driven. Knowing everything about everything is impossible, and there will always be diseases that a GP or many GPs will not know everything about. So specific training, it's probably very hard to work out who needs it, how to deliver it, where it would go to and what benefit it would actually make to the patients.

I think general training -- or general information and information sharing, both to doctors and to the public, that, "You may have had a transfusion in the past; if you've not discussed this with your doctor, please discuss it with them at some point" is probably a more useful way of that people who are affected by it to come forward. Because while you're -- a patient coming to see a GP about a specific problem may only still deal with that specific problem while they're there, because that's the priority at that moment.

How you would then -- what the extra training would achieve may not be as useful as having more information generally that infected blood was the source of HCV.

Q. Finally, do you think there's a risk that because previously GPs might have thought that everyone infected

through infected blood would be identified in the look-back, then even now that might result in barriers to identifying people with hepatitis C who haven't yet been diagnosed?

A. I think identifying people that haven't been diagnosed is always challenging, both -- patients will need to know that they've had a transfusion and come forward from that side. Just GPs being aware -- I think these days people are more aware, certainly with the Inquiry being on the news and hearing so much about it over the past years, that we know there are patients still coming forward who are being diagnosed now -- I saw on some of the footage of the Inquiry -- 30 years later, for the first time this year. And I think (unclear) GPs are aware of that, and doctors are increasingly aware there could be more information shared that the look-back wasn't as effective as might have been imagined.

MS FRASER BUTLIN: Sir, I have no further questions. Do you have anything you would like to add?

SIR BRIAN LANGSTAFF: Yes, I do.

Very early on in your evidence, you were talking about CPD, and you told us that a lot of GPs may choose to go to an independent provider, and that the college had no control over the independent provider. You will know as we all do, I think, that if you go onto the

Internet and look at something which is related to healthcare, you will get -- how can I put this -- you will get a number of websites which are more reliable than others, which are certainly less reliable. And some of the less reliable ones may be thought to have more commercial influence than others.

A. Yeah.

SIR BRIAN LANGSTAFF: You're nodding. Is there any process or have you thought of any process by which the CP course offered by -- CPD course offered by an external provider is validated or approved, at least as to the curriculum and content, generally speaking, by the college?

A. The college hasn't been involved in that because we work at providing that curriculum and content for our own CPD. I know that other CPD companies take it as seriously as we do in their own way, and probably within general practice, although there are many things on the web that you could go to look at, there are a number of companies that run very effective courses and -- up to date, based on NICE guidance, and I think increasingly NICE guidance is used as the standard we all hold our CPD to. So if someone who is teaching outside what NICE or SIGN, in Scotland, are saying, people would question where the evidence is coming from. So I think doctors

and scientists are looking for evidence-based courses and evidence-based information, but as a college we haven't tried to get involved in the quality of other people's work.

SIR BRIAN LANGSTAFF: The reason I ask in particular is that in certain professions, and I'm thinking of the Bar in this, amongst others, which I obviously have had experience of, my understanding is that the CPD courses or courses which are offered by the person who takes them as part of their CPD are actually approved as having so many hours CPD by the -- in this case, the Council of the Bar. That's the case, is it not?

MS FRASER BUTLIN: Not anymore, sir.

SIR BRIAN LANGSTAFF: Not anymore? Right. Well, it used to be the case.

MS FRASER BUTLIN: It did.

A. We do provide -- if provider wants a course accredited by us, we do offer that as a service from the college, and that would then be a stamp from the college, a Kite Mark, effectively, to say: this is RCGP recognised standard of information you're about to get. But that's very much a choice for the provider to make, not that we go looking for it or insist on it.

SIR BRIAN LANGSTAFF: Yes. Thank you.

The second is this: again, it's relating to

education. What we've heard a lot of, we've heard quite a bit of it today, and you yourself have been frank about the demands upon a GP's time, being a GP in these days, we were told in very clear terms by this morning's panel, involves a certain amount of stress, if you like, which has led to the general profile of the profession aging, people being less inclined to do it. And two things arise out of this. First is, is there any particular training available, whether it's CPD or general, for the GP themselves? They're one party to a conversation, after all, with the patient, in terms of their own resilience and their own -- how to deal with the stresses which they may experience in practice, particularly given the unpredictable demands that it may bring?

A. Increasingly with the workload and workforce pressures in general practice, and we know that the number of GPs full time equivalence is falling over the past years, whilst the population and the demands have risen, and we have 1.3 million consultations per day in general practice now, compared to about 1 million before the pandemic, that GPs are really struggling to maintain their resilience, as you say.

So many -- both the college and other CPD providers and local networks are working very hard to maintain GP

wellbeing and health and resilience within that with courses with support. Unfortunately, what we see is GPs do do the job, they work 12-hour days very often but they do fewer of them to maintain the space in their lives and work-life balance to allow them to be able to do the full amount of work on the days when they're in. So we're seeing a knock-on in the profession that the GP numbers fall because the workforce or the demands of the workload are so high on the days they work.

So very often people are concentrating -- and we do it within the faculty structure in the college -- provide courses on wellbeing and support and resilience for the GPs, so they can actually learn skills as well as support to get through it.

SIR BRIAN LANGSTAFF: May I ask, the job you do is voluntary, is it?

A. I'm paid a small amount for the sessions I do. So I work for the college as an officer. So in that role I'm paid.

SIR BRIAN LANGSTAFF: So in that role, you have time which is remunerated?

A. Yes.

SIR BRIAN LANGSTAFF: Is that true of those to who sit on the council of the college?

A. No, as a council member people do it voluntarily. So

I was a council member for some years before I was an officer and that's a voluntary role.

SIR BRIAN LANGSTAFF: So they will be giving their time, which they can ill afford to give, given the demands of practice, in order to deal with the general interests of the profession. This is maybe a difficult question for you to answer but does that risk the quality of leadership being less strong than it used to be?

A. As a GP leader, it's a difficult question to answer, but --

SIR BRIAN LANGSTAFF: Well, the word is "risk". I'm not asking you to say, "Yes, that's the case", unless you think that is.

A. No, I think the quality of leadership we're seeing coming through, particularly from our younger members as well in the college, is as strong as it always has been but people are now seeing that as part of their career and factoring the time required in their workload but as a voluntary role. So we have volunteers working in our faculties, we have volunteers working on various projects through the college on the assessment of evidence and other parts and these people will see it as they -- it helps balance some of the resilience from practice.

If they're doing a different job for part of the

week, even if it's as a volunteer, it helps to stimulate the brain, it keeps them interested in the work, rather than just having to constantly go through large numbers of -- or large amounts of work on a day in practice.

SIR BRIAN LANGSTAFF: Thank you. The next question again arises really out of this morning's exchanges in evidence. We were told that, even though in Scotland it's now mandated that the discharge letter should refer to a blood transfusion, in about 50 per cent of cases it doesn't. Looking at the discharge letters you will have seen and those in your practice will have seen, so far as you are aware, is it the case that it is probably 50 per cent or less of those letters will refer to a transfusion which, so far as -- again, depends on the information you've got about it -- so far as you know has or has most probably been given?

A. I think the number of discharge letters with blood transfusion on them is probably quite small, so most of my patients in the elderly population are going in with medical problems that don't need transfusion. Sometimes they do. But the numbers that we're receiving are quite small numbers saying transfusion on them.

SIR BRIAN LANGSTAFF: So the probability is that they're not recording all of them?

A. I don't know about the recording in hospital.

I wouldn't want to guess what they record.

SIR BRIAN LANGSTAFF: You can't know without that --

A. No, we can't know without --

SIR BRIAN LANGSTAFF: -- but if, as a matter of general practice, you might expect a certain proportion of patients who have been in hospital for various conditions to have had transfusions and if you're getting actually very few letters which say "Yes, so and so had a transfusion of whatever", then chances are that some are not being recorded.

A. Possibly, yes.

SIR BRIAN LANGSTAFF: Thank you. That's all I ask.

MS FRASER BUTLIN: Dr Mulholland, is there anything else you would like to add?

A. May I make a statement?

MS FRASER BUTLIN: Please do.

A. Good afternoon, thank you. I'm Michael Mulholland, a GP in Buckinghamshire and honorary secretary of the Royal College of GPs. The RCGP is the largest medical royal college and it represents over 54,000 family doctors in the UK. Our mission since we were founded 70 years ago has always been to raise the standards of patient care I've been asked by my college in coming here today to add to my evidence that we send our sympathy to everyone whose life has been impacted and to their families.

Lessons must be learnt from the experience and the college will play our part in preventing anything similar happening in the future.

SIR BRIAN LANGSTAFF: Thank you for that, and thank you for your evidence, particularly given what we've just been saying about the busyness of a GP's practice and role.

THE WITNESS: Thank you.

MS FRASER BUTLIN: Sir, that concludes the evidence for today.

Tomorrow we will be hearing from Professor Sir Jonathan Van-Tam.

SIR BRIAN LANGSTAFF: Yes, Professor Sir Jonathan Van-Tam tomorrow, 10.00.

(3.34 pm)

(The hearing adjourned until 10.00 am the following day)

I N D E X